Comparison of Ultrasonic Nebulisation with Dexmedetomidine versus Clonidine for Post-Operative Sore Throat-A prospective Observational Study

Thesis submitted to the faculty of

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For the award of the degree of MD in the subject of

Anaesthesiology and Critical Care Medicine

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Following members attended the meeting:

1. Prof. D. K. Pal, Professor & HoD Community Medicine, GMC, Bhopal…Chairperson
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3. Prof. Amit Agrawal, Professor of Neurosurgery, AIIMS, Bhopal……Member
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The AIIMS, Bhopal IHEC-PGR approves your research protocol. All research related activities must begin only after the date of this approval. The validity of this approval is till two years from the date of issuance. Please submit a closure report / renewal request before expiration of the validity for this approval.

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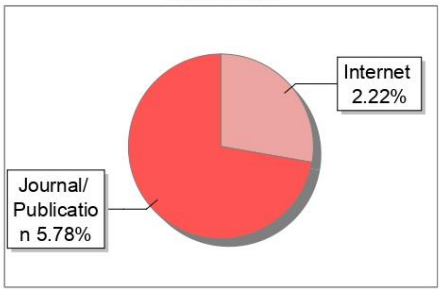

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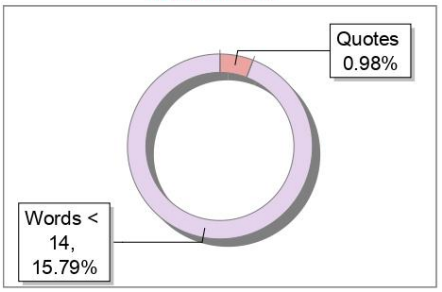

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ABBREVIATION	EXPANDED FORM
POST	Post-operative sore throat
GA	General anaesthesia
ETT	Endotracheal tube
NSAIDS	Non-steroidal anti-inflammatory drugs
SBP	Systolic blood pressure
DBP	Diastolic blood pressure
HR	Heart rate
MAP	Mean arterial pressure
RCT	Randomised controlled Trial
IV	Intravenous
ASA	American society of anaesthesiologist
NPO	Nil per oral
MAC	Minimum alveolar concentration
BPM	Beats per minute
inj	Injection
NIBP	Non-invasive blood pressure
mcg	Micro grams

INTRODUCTION

Post-operative sore throat (POST) is defined as the discomfort that patients frequently experience during the post -operative recovery after surgery, under general anaesthesia (GA) (1). The incidence of POST varies from 18-65% in different studies. (2) (3) The highest POST incidence was observed after tracheal intubation (45.4%) when compared to laryngeal mask airway (17.5%) and open mask (3.3%). (4)

Post- operative sore throat is caused by aseptic inflammation of the pharyngeal mucosa caused by localised damage to the mucosa of pharynx during laryngoscopy or as an injury to the tracheal tissues either during intubation or extubation. (5) Etiology of POST is multifactorial including choice of airway device, high ETT cuff pressure, surgical manipulation of airway, airway suctioning and the type and length of surgery. (6)

Although treating doctor may ignore POST, it can make patients very ill and depressed. It makes harder for patients to recover and communicate with healthcare providers. It can make difficult for patients to swallow. In severe cases a sore throat can lead to coughing and respiratory issues. (1) POST can significantly reduce the patients' satisfaction level and affect their recovery. Moreover, POST increases the cost of hospitalization for patients. Therefore, reducing the incidence and severity of POST is urgently needed to improve patients' postoperative satisfaction and alleviate their burden of hospitalization costs.

Many prophylactic measures are used to decrease the incidence of POST like the use of smaller sized endotracheal tubes with low intracuff pressure. Although the role of endotracheal tube

intracuff pressure is still unclear. But it would seem that excessive endotracheal tube intracuff pressure and nerve compression-induced neuropraxia are linked to nerve palsies. (5)

Many non-pharmacological and pharmacological trials have been used for attenuating POST with no proven single modality. The pharmacological methods used to reduce POST include the use of beclomethasone gel, gargling with azulene sulfonate, ketamine, clonidine, lidocaine gel, steroids (triamcinolone paste 0.1%, betamethasone gel 0.05%), liquorice, N methyl D aspartate receptor antagonists and topical NSAIDS like benzylamine hydrochloride. (7)

These conventional methods may not effectively prevent POST, as individual responses to these interventions can vary and many of these methods provide only temporary relief and may not offer long- lasting prevention.

Nebulisation is a non-invasive technique with a quick onset of action and strong absorption due to the respiratory mucosa's substantial surface area. Nebulisation avoids adverse effects associated with the intravenous drug administration. Furthermore, issues with temporary nasal discomfort, coughing, and vocal cord irritability related laryngospasm common with intranasal route can be prevented. Nebulization is easier than gargling and is tolerated by more patients because atomization can avoid the bitter taste of the medicine. Aspiration is also less because less volume is used compared to the volume required for gargling (1)

Ultrasonic nebulisation is a newer approach that can be used for airway humidification. Ultrasonic nebulisation deposits ultrasonic mists of a local anaesthetic directly over the mucosa. The fine mist generated by ultrasonic nebulisers allow for a high percentage of the

medication to be inhaled and reach the target site in the respiratory system. This increases the drugs therapeutic efficacy.

In previous studies, nebulised form of different drugs like ketamine, ketamine with clonidine, dexmedetomidine, dexamethasone, magnesium sulphate, budesonide, lignocaine are used to decrease POST when administered in nebulised form in preoperative period. (8)(9)(10)(11)(12)(13)

Alpha-2 (α_2) adrenergic agonists like Dexmedetomidine and clonidine in combination with ketamine is recently explored for the prevention of POST. (1)(8)(12)(13)

Dexmedetomidine is a colourless, tasteless and odourless drug with a selective alpha2 adrenergic agonistic action. It is commonly used as an intravenous medication for sedation in various clinical settings, including intensive care unit, operating rooms, and procedural suites. It provides sedation without causing significant respiratory depression, making it preferred choice for maintaining sedation in mechanically ventilated patients. It leads to decrease in sympathetic nervous system activity, resulting in reduced heart rate and blood pressure. It has rapid onset and offset of action, allowing for precise control of a patients level of sedation. It produces analgesia, reduces delirium and agitation, perioperative sympatholysis, cardiovascular stabilising effects and preservation of respiratory functions. (14) Various doses and delivery methods, including intravenous, intranasal, intramuscular, and nebulised, had been studied to reduce hemodynamic response to intubation. The dexmedetomidine has bioavailability of 65% via the nasal cavity. (15)

Clonidine is a non-selective alpha 2 adrenergic receptor agonist that selectively stimulates post synaptic alpha-adrenergic receptors in the depressor site of vasomotor centre of the medulla oblongata in the region of the nucleus of the solitary tract or locus coeruleus.

Activation of these central alpha-adrenergic receptors diminishes the efferent sympathetic neuronal vasoconstrictor tone of the heart, kidneys, and peripheral vasculature causing vasodilation and lowering blood pressure. Various studies have reported that clonidine produces antinociception regardless of the route of administration (central or peripheral).

The topical administration of clonidine causes antinociception by blocking the emerging pain signals at peripheral terminals through α2-adrenoceptors without producing undesirable side effect observed after systemic administration. (16)(17)(18)(19)(20)

Although both drugs have alpha-2 adrenergic agonistic action, dexmedetomidine is 8-10 times more selective towards alpha2 adrenergic receptors than clonidine. However dexmedetomidine and clonidine has already been in use in a nebulised form and being a highly lipid soluble that are well absorbed from the body when administered transmucosally (1)

Various studies are done on effect of dexmedetomidine nebulisation on post-operative sore throat. (1) (14) (15). But there is no study showing the effect of nebulised clonidine on POST reduction.

There is research gap regarding comparison of effectiveness of dexmedetomidine and clonidine administered preoperatively through ultrasonic nebulisation in decreasing POST.

This study intends to evaluate and compare the effectiveness of ultrasonically nebulized dexmedetomidine and clonidine in alleviating post-operative sore throat in the patients undergoing elective laparoscopic cholecystectomy under general anaesthesia.

REVIEW OF LITERATURE

1. A study on "Dexmedetomidine nebulization impairs POST in patients undergoing thyroidectomy. It was comparative study with ketamine nebulization" In this study, people were randomly divided into two groups of 50 each. Group 1 were nebulised with ketamine 50 mg (1 ml) with 4 ml of saline, while group 2 were dexmedetomidine 50 micrograms (1 ml) with 4 ml of saline over 15 minutes. GA was administered 15 minutes after the nebulization. POST monitoring was performed at 0,2,4,6,12,24 hours after extubation. The overall incidence of POST in this study was 17%. Seven patients in the ketamine group (14.3%) and dexmedetomidine group (20.4%) experienced POST ($p = 0.424$).

   After nebulization, significant increases in heart rate, blood pressure, and diastolic blood pressure were observed in the ketamine group.This study concluded that dexmedetomidine nebulization may be a safe and superior alternative to ketamine nebulization for POST suppression, thereby reducing hemodynamic abnormalities. (1)

2. **Hyuckgoo Kim, Hyojin Kwon *et al*** in 2020, conducted a study to evaluate the effect of dexmedetomidine and remifentanil on POST. Seventy-four patients undergoing thyroidectomy were randomized to receive either dexmedetomidine (group D) or remifentanil (group R). After induction of anesthesia, group D received dexmedetomidine 1 μg/kg for 10 minutes, followed by continuous infusion of dexmedetomidine 0.3–0.6 μg/kg/hour during surgery. Group R received 3-4 ng/ml remifentanil during induction followed by an infusion of 1.5-2.5 ng/ml remifentanil during surgery. POST at rest and swallowing were assessed in consecutive periods (0-1, 1-6 and 6-24 h) during the first 24 h. Hoarseness and postoperative pain scores were

also assessed. The study found that the incidence of POST at rest (0-1, 1-6 and 6-24 hours) and swallowing (1-6 and 6-24 hours) was lower in group D than in group R. Postoperative severity and effect. of POST hoarseness was also lower in the D group than in the R group at each time period. (21)

3. "Comparison of nebulized ketamine and ketamine with clonidine in POST", patients were divided into two groups. Patients in group K were nebulized with 1 mL (50 mg) of ketamine and 3 mL of normal saline. Group KC was nebulized with ketamine 1 ml (50 mg) plus 1 ml clonidine (50 mg) plus 2 ml normal saline. Here, it was concluded that preoperative nebulization with ketamine and clonidine more effectively reduces POST without adverse effects compared to preoperative ketamine.(13)

4. **Satyajeet Misra *et al*** studied "Effect of preoperative dexmedetomidine nebulization on hemodynamic response to laryngoscopy and intubation - a randomized control trial" and found that nebulized dexmedetomidine 1 mcg/kg in 3-4 mL normal saline attenuated the increase in cardiac output not SBP. Dexmedetomidine nebulisation reduced the intraoperative consumption of anesthetics and analgesics. They found that after laryngoscopy, there was no effect on early postoperative nausea, vomiting, sore throat, or increased incidence of adverse events. (22) Nebulized dexmedetomideone may be a low-cost alternative to intravenous administration for short-term operations.

5. **Velayudha Sidda Reddy *et al*** showed moderate analgesia with a ceiling effect at a dose of 0.5 mcg/kg. They chose a dose of 0.5 micrograms/kg dexmedetomidine given slowly over 10 minutes. The dose of clonidine is 1.5-2 times higher than the dose of dexmedetomidine. Thus, a dose of 1.0 micrograms/kg clonidine was chosen for the

study. 75 patients were divided into three groups of 25 each. Group DE received dexmedetomidine 0.5 micrograms/kg, group CL received clonidine 1.0 micrograms/kg, and placebo group PL received 10 ml normal saline intravenously before subarachnoid anesthesia. The study concluded that the degree of sensory blockade was greater with dexmedetomidine than with clonidine or placebo. Dexmedetomidine also increased the time to the first postoperative pain medication request compared with clonidine and placebo. The study concluded that intravenous dexmedetomidine was superior to intravenous clonidine for sedation and postoperative analgesia. (23)

6. A study performed to compare intravenous dexmedetomidine and clonidine to suppress the hemodynamic response during laryngoscopy and intubation. Group I received 0.9% normal saline (placebo), group II received 0.5 micrograms/kg dexmedetomidine, and group III patients received 3 micrograms/kg clonidine, 15 patients in each group. The results showed that mean SBP scores were higher in group 1 (normal saline) with both drugs. The mean DBP scores of both groups were similar in different time periods and were slightly higher in group 1, especially after 30 minutes compared to group II. The authors concluded that both groups were equally effective in reducing the hemodynamic response to endotracheal intubation. (41)

7. **Mahjoubifard M *et al*** investigated the comparison of dexmedetomidine, lidocaine and fentanyl in reducing the hemodynamic response to laryngoscopy and intubation in cardiac surgery patients. They concluded that all three drugs were effective in controlling HR, but dexmedetomidine caused bradycardia at 3, 5, and 10 min. Lidocaine increased MAP at 1 minute after intubation, whereas dexmedetomidine decreased MAP at 5 and 10 minutes after intubation. Post-induction changes in HR and

MAP were smaller in the fentanyl group, and fentanyl more effectively inhibited hemodynamic responses to laryngoscopy and intubation in patients undergoing cardiac surgery, as post-induction changes in HR and MAP were greater in the lidocaine group than in the fentanyl group. group MAP also increased in the lidocaine group at initial recording, so it can be said that fentanyl stabilizes lidocaine more effectively. (24)

8. **Jin Young Lee *et al*** investigated the prevalence and risk factors of postoperative sore throat after endotracheal intubation in Korean patients. Patients undergoing all types of elective surgical procedures with endotracheal intubation and general anesthesia were included in this prospective study. Patients were classified into group S (those with POST) or group N (those without POST). In this study, the overall incidence of POST was 57.5%. The analysis showed that significantly more patients in the S group had cough and hoarseness in the post-anesthesia care unit compared to the N group. Analysis showed that intra-cuff pressure>/-17 cm H2O was associated with POST. They concluded that intracuff pressure >/- 17 cmH2O and cough were risk factors for POST in Korean patients. To prevent POST testing, peak monitoring and continuous exposure during anesthesia is required.(25)

9. **Neema Ann Sabu *et al*** investigated the effect of nebulized dexmedetomidine on hemodynamic response during intubation. Patients scheduled for surgery under general anesthesia received either nebulized dexmedetomidine 10 minutes before intubation (group A) or an inj. lignocaine 90s before intubation (group B). Post-intubation hemodynamic parameters were compared in both groups. Dexmedetomidine nebulization showed a statistically significant levelling of the hemodynamic response during the first minute after intubation in group A. This was observed for variables such

as HR, DBP and MAP. There was no significant difference in systolic blood pressure at any time. In addition, there were no significant changes in the variables at 5 and 10 minutes after intubation. The dose of propofol required for induction was significantly lower in group A compared to group B. Dexmedetomidine nebulization before laryngoscopy, and intubation significantly reduced the hemodynamic response to intubation.(26)

10. **F.E. McHardy *et al*** in their study concluded that, postoperative sore throat symptoms such as sore throat, hoarseness, and dysphagia are common and are associated with trauma to the larynx and pharynx. Careful airway management technique and appropriately sized tracheal tubes are essential. Lubricants containing local anesthetics do not appear to be helpful and may actually be harmful. Tracheal cuff pressure monitoring should be considered to reduce postoperative sore throat. (5)

11. **K. El-Boghdadly, C.R. Bailey and M.D. Wiles *et al*** in their study concluded that, postoperative sore throat has been reported to occur in up to 62%. Female sex, younger age, preexisting lung disease, prolonged duration of anesthesia, and the presence of a blood-stained trachea during extubation are associated with the greatest risk in adults undergoing tracheal intubation. Tracheal intubation without neuromuscular blockade, use of double-lumen tubes and high tracheal cuff pressure can cause postoperative sore throat. (7)

12. **Jaensson M *et al*** the main goal of this study was to determine whether the development of sore throat after anesthesia depends on the size of the endotracheal tube (ETT). When Comparing changes between pre- and post-operation levels, there was also a clear difference between groups, P value 0.002. In addition, ETT 7.0 (38.8%) experienced more severe throat pain than ETT 6.0 (18.8%), P value 0.02. The incidence of hoarseness did not differ between groups.(6)

13. Study on the Comparison of Intravenous Versus Nebulized dexmedetomidine for Laryngoscopy and Intubation-Induced Sympathoadrenal Stress Response Attenuation was conducted by **Vishwadeep Singh *et al*** The effects of preoperative dexmedetomidine nebulization on laryngoscopy/intubation hemodynamic response, hemodynamics, analgesic use, and postoperative sore throat were assessed. The administration of nebulized dexmedetomidine (1 g/kg in 3 to 4 mL of 0.9% saline) and intravenous dexmedetomidine (1 g/kg over 10 minutes) 30 minutes before to the induction of anesthesia was randomized for 120 patients in ASA I and II undergoing elective operations that required tracheal intubation. Following the laryngoscopy and for the duration of the surgery. Non-invasive blood pressure and heart rate were monitored for a total of 10 minutes. The recovery from anesthesia, postoperative sore throat, and consumption of intraoperative analgesics were evaluated. At three minutes, there was no discernible hemodynamic difference between the two groups (27)

14. The primary goal of the study done by **N. Gupta *et al*** was to compare the efficacy of intravenous dexmedetomidine and clonidine as adjuvants to low dose opioid (fentanyl)

for attenuating the hemodynamic response to laryngoscopy and tracheal intubation. Comparing the perioperative dose requirements of fentanyl and thiopentone, the length of postoperative analgesia, and searching for adverse events in all three groups were the secondary goals. One hundred twenty (120) patients (ASA I or II) registered for elective surgery under general anesthesia as part of this randomized controlled trial. Dexmedetomidine (1 g/kg) intravenously was administered to Group D. Group C received intravenous clonidine (1g/kg) with intravenous fentanyl (1g/kg), Group D received intravenous fentanyl (2g/kg), and Group F received both intravenous fentanyl and intravenous dexmedetomidine (1g/kg). At baseline, after the study drug at 5, 10, and 15 minutes, after induction, intubation (0 min), and 1, 3, 5, 10, and 15 minutes after intubation, heart rate and mean arterial pressure were measured. Dexmedetomidine was able to entirely eradicate the increase in HR and MAP that occurred during laryngoscopy and intubation, which was observed to be reduced in the clonidine group compared to the fentanyl group. Dexmedetomidine considerably reduced the need for thiopentone and fentanyl, but clonidine significantly increased the length of time until the first rescue analgesia. (28)

15. **V. Gupta *et al*** conducted a RCT to examine the effects of IV fentanyl and IV clonidine on hemodynamic during laparoscopic cholecystectomy. A total of 80 patients (ASA I or II) who had been scheduled for elective laparoscopic cholecystectomy were divided into two groups at random. I.V. Clonidine (2mcg/kg) was given to Group C, whereas I.V. Fentanyl (2mcg/kg) was given to Group F. Baseline (before study drug), after study drug, after I.V. induction, at intubation 0, 1, 3, and 5 minutes after intubation, at the beginning of pneumoperitoneum, and subsequently every 15 minutes until the

completion of operation were all used to monitor heart rate and mean blood pressure. He discovered that both intravenous fentanyl and intravenous clonidine were effective at reducing the perioperative hemodynamic response during laryngoscopy, intubation, and pneumoperitoneum. (29)

Ultrasonic atomizers use piezoelectric transducers that produce ultrasonic waves when a current is applied the liquid solution in a small reservoir is usually placed above the piezoelectric transducer. The sensor vibrates very quickly at a frequency of 1-3MHz. These vibrations create pressure waves in the liquid and due to these pressure waves small bubbles or cavities form in the liquid and they burst or burst due to frequent vibrations. The collapse of these bubbles causes shock and stress in the liquid, causing it to break up into smaller droplets. These droplets are then released from the mouthpiece in the form of an aerosol mist. Ultrasonic atomization produces very fine and uniform droplets, generally in the 1-5 micron range. This small size is ideal for inhalation into the lungs and allows effective respiratory delivery. (30)

AIMS & OBJECTIVES

AIM

To compare the effect of ultrasonic nebulization with dexmedetomidine and clonidine on post-operative sore throat in patients undergoing elective laparoscopic cholecystectomy under general anaesthesia with endotracheal tube.

PRIMARY OBJECTIVES

To estimate and compare the efficacy of ultrasonic nebulisation with dexmedetomidine and clonidine on post- operative sore throat at 10 minutes, 1 hour, 6 hour, 12 hour and 24 hour after extubation in patients undergoing elective laparoscopic cholecystectomy under general anaesthesia with endotracheal tube.

SECONDARY OBJECTIVES

To estimate and compare the effect of ultrasonic nebulisation with dexmedetomidine and clonidine on heart rate, systolic blood pressure, diastolic blood pressure, mean arterial blood pressure at baseline, at induction, at laryngoscopy, at intubation, 1min after intubation and 5 min after intubation in patients undergoing elective laparoscopic cholecystectomy under general anaesthesia with endotracheal tube.

MATERIALS AND METHODOLOGY

PLACE OF STUDY - Department of Anesthesiology, All India institute of medical sciences, Bhopal.

SETTING - Operation theatre, Post anesthesia care unit, AIIMS Bhopal

DURATION OF STUDY - This was a single center study conducted over a period of 18 months.

NUMBER OF PATIENTS - A total of 78 patients. 40 patients in dexmedetomidine group and 38 patients in clonidine group.

STUDY DESIGN - A prospective observational comparative cohort study.

STUDY PARTICIPANTS - Patients who underwent elective laparoscopic cholecystectomy under general anesthesia with muscle relaxation and endotracheal intubation were included in this study.

INCLUSION CRITERIA -

1. All patients (18-65 years) of either gender giving consent for the study.
2. Patients with American Society of Anesthesiologist physical status (ASA) Grading I & II.

EXCLUSION CRITERIA -

1. Non consenting patients.
2. Allergy to dexmedetomidine or clonidine.
3. Current upper respiratory tract infections, pre-existing sore throat and/or hoarseness.
4. Patients using steroids or nonsteroidal anti-inflammatory drugs.
5. Patients with chronic obstructive pulmonary disease, asthma.

6. Pregnant patients.
7. Any history of difficult intubation, loose teeth.
8. Difficult intubation requiring more than one attempt or mallampatti grade >2.
9. Patients not extubated at the end of surgery.
10. Patients with sinus bradycardia, atrioventricular block, cardiac disease.
11. Patients with a history of pre-operative sore throat.

METHODOLOGY

This prospective observational study was started after getting institutional ethical clearance (IHEC-PGR/2021/PG/Jul/03) and CTRI (Clinical Trials Registry-India) registration no. CTRI/2022/04/042238. Written informed consent were taken after thorough explanation of the purpose and procedure of the study.

SAMPLE SIZE CALCULATION

The sample size was calculated according to the formula:

Sample size N =	$\frac{r+1}{} \times \frac{(z_{\alpha} + z_{1-\beta})^2 * (p1*(1-p1) + p2*(1-p2))}{(p1 - p2)^2}$

The sample size for the study was based on a study by Thomas D *et al* 2020 (1) who reported the rate of sore throat in the two groups as follows:

Sore Throat	
Dexmedetomidine	Clonidine
20.4%	0%

r (ratio of number of patients in each arm) = 1

p1 (prevalence in cases) = 0.204

p2 (prevalence in controls) = 0.0

Type I error (α) = 5%, $\underline{z_{\alpha}}$ = 1.96

Type II error (β) = 20%, Power = 1 – β = 80%, $\underline{z_{1-\beta}}$ = 0.842

Based on the formula given above, using the mentioned values, the sample size required is = 33 per arm.

Assuming 10 % drop out and keeping feasibility issues in mind, 37 patients in each group was calculated for the study.

ANAESTHESIA TECHNIQUES

In the preoperative area patient information sheet was given to all patients participating in study in which study protocol and procedure was explained to them thoroughly. Written informed consent was obtained from all the patients.

The following baseline demographic and clinical characteristics were recorded for all patients in preoperative area before shifting the patient to operating room: age, sex, ASA physical status, non -invasive Blood Pressure, Heart Rate & SPO2 as baseline parameter. Standard ASA provided NPO guideline were followed for the study.

As this is a non-randomised study, the choice of agent for nebulisation was decided on the discretion of the anaesthesiologist in charge.

In one group, nebulisation was done with dexmedetomidine whereas in other group, nebulisation was done with clonidine.

Dexmedetomidine group – 40 Patients were nebulised with 50 mcg dexmedetomidine in 4 ml normal saline.

Clonidine group – 38 Patients were nebulised with 100 mcg of clonidine diluted in 4 ml normal saline.

Nebulisation was done with help of an ultrasonic nebuliser (Sahyog Wellness Ultrasonic Nebuliser Machine (MY-520A) [INDIA] with the help of a wall attached oxygen drive source 15 minutes prior to inducing the patient for 15 minutes.

Figure 1 - Ultrasonic nebuliser (Sahyog Wellness Ultrasonic Nebuliser Machine (MY-520A) [India]

After preoxygenation with 100% O_2 at 6 litre / minute, induction was achieved with intravenous fentanyl (1-2 μg/kg), propofol (2mg/kg) titrated to the effect of loss of verbal response, vecuronium 0.1 mg/kg and after securing airway with endotracheal intubation, anaesthesia was maintained with Isoflurane (0.5-1 MAC) and O_2:N_2O (40:60). Smooth laryngoscopy and intubation was performed by a well experienced anaesthesiologist, which lasted less than 15 sec.

Normocapnia was maintained with controlled mechanical ventilation with end-tidal carbon-dioxide tension values ranging from 30-35 mmHg. Euvolemia was maintained with crystalloid infusion. Normothermia was maintained throughout the surgery with forced air warming device and infusion of warm fluids. Antiemetic in the form of Ondansetron 4mg IV was given 30 min before end of surgery. Gentle extubation of the patient was done after reversal of neuromuscular blocking agent after completion of the surgery.

STUDY VARIABLES AND DATA COLLECTION

1. Demographic data: Patients UHID/CR number, name, age (in years), sex.
2. Diagnosis and planned surgery, Cormack - Lehane grade at the time of laryngoscopy
3. Duration of surgery
4. Patients' vitals: Heart rate (bpm), systolic blood pressure, diastolic blood pressure, mean arterial pressure and spO2 (%) at baseline, at induction, at laryngoscopy, at intubation, 1min after intubation and 5 min after intubation, and after extubation.
5. Airway pressures (cm of H2O) and ETT Intra Cuff Pressure at intubation, during gas insufflation of abdomen and at extubation.
6. During the post-operative period, sore throat was evaluated at 10 minutes, 1 hour, 6-hours, 12 hours and 24 hours after extubation.
7. Grading of sore throat - was identified according to this classification Aqil M *et al* (31)
   0- No sore throat
   1- Mild sore throat (complaints of sore throat on asking)
   2- Moderate sore throat (complaints of sore throat on his/ her own)
   3- Severe sore throat (change in voice or hoarseness associated with throat pain)

Patient developed sore throat in any group was treated as per department protocol.

PRIMARY OUTCOME

The primary outcome of the study was to determine whether ultrasonically nebulised dexmedetomidine and clonidine in the preoperative period is effective in reducing the postoperative sore throat and which drug is comparatively better for achieving primary

objective in patients who underwent elective laparoscopic cholecystectomy under general anesthesia

SECONDARY OUTCOME

The secondary outcome of the study was to determine whether ultrasonically nebulised dexmedetomidine or nebulised clonidine provide more hemodynamic stability in patients who underwent elective laparoscopic cholecystectomy under general anesthesia.

STUDY EQUIPMENTS

1. Nebulisation was done using ultrasonic nebulizer - Sahyog Wellness Ultrasonic Nebulizer Machine (MY-520A) [INDIA] which comes with nebulizer kit and adult masks.

2. ETT intra cuff pressure was measured by CUFF MANOMETER- MCP Shock Resistant Palm Blood Pressure Monitor HS201 [INDIA] which is available in modular OT department of Anesthesiology.

STATISTICAL ANALYSIS

- Data was coded and recorded in MS Excel spreadsheet program. SPSS v23 (IBM Corp.) was used for data analysis.
- Descriptive statistics was elaborated in the form of means/standard deviations and medians/IQRs for continuous variables, and frequencies and percentages for categorical variables. Data was presented in a graphical manner wherever appropriate for data

visualization using histograms/box-and-whisker plots/column charts for continuous data and bar charts/pie charts for categorical data.

- Group comparisons for continuously distributed data was made using independent sample 't' test when comparing two groups, and One-Way ANOVA when comparing more than two groups. Post-Hoc pairwise analysis will be performed using Tukey's HSD test in case of One-Way ANOVA to control for alpha inflation. In data which was non-normally distributed, appropriate non-parametric tests in the form of Wilcoxon Test/Kruskal Wallis test was used for these comparisons.
- Chi-squared test was used for group comparisons for categorical data. In the cases where expected frequency in the contingency tables was found to be <5 for >25% of the cells, Fisher's Exact test was used instead.
- Linear correlation between two continuous variables was explored using Pearson's correlation (in normally distributed data) and Spearman's correlation (for non-normally distributed data).
- Statistical significance was kept at $p < 0.05$.

RESULTS AND OBSERVATION

A total of 78 patients of age group 18-65 years undergoing laparoscopic cholecystectomy enrolled over a period of 18 months. Out of which 40 patients were nebulized with dexmedetomidine and 38 patients were nebulized with clonidine.

The demographic variables are shown in table 1.

TABLE 1. DEMOGRAPHIC INFORMATION OF PARTICIPANTS

Parameters	**Drug**		**p value**
	Dexmedetomidine (n = 40)	**Clonidine (n = 38)**	
Age (Years)* **	42.80 ± 10.41	37.68 ± 9.24	
Age			0.390 [2]
18-30 Years	5 (12.5%)	9 (23.7%)	
31-40 Years	14 (35.0%)	16 (42.1%)	
41-50 Years	10 (25.0%)	8 (21.1%)	
51-60 Years	10 (25.0%)	5 (13.2%)	
61-70 Years	1 (2.5%)	0 (0.0%)	
Gender			0.177 [2]
Male	24 (60.0%)	17 (44.7%)	
Female	16 (40.0%)	21 (55.3%)	
Duration (minutes)	163.25 ± 36.89	156.32 ± 43.77	0.480 [3]

2: Chi-Squared Test, 3: Wilcoxon-Mann-Whitney U Test

The mean age of the patients were 42.80 ± 10.41 years and 37.68 ± 9.24 in dexmedetomidine and clonidine group respectively (P = 0.390).

60% patients were male whereas 40% were female in the dexmedetomidine group. 55% were female whereas 44.7% were male in the clonidine group. (P = 0.177).

This study only includes laparoscopic cholecystectomy surgery, the duration was 163.25 ± 36.89 minutes in the dexmedetomidine group and 156.32 ± 43.77 minutes in the clonidine group (P = 0.480).

All these demographic variables were comparable in both groups.

Figure 2 shows - Association between drug and age (years)

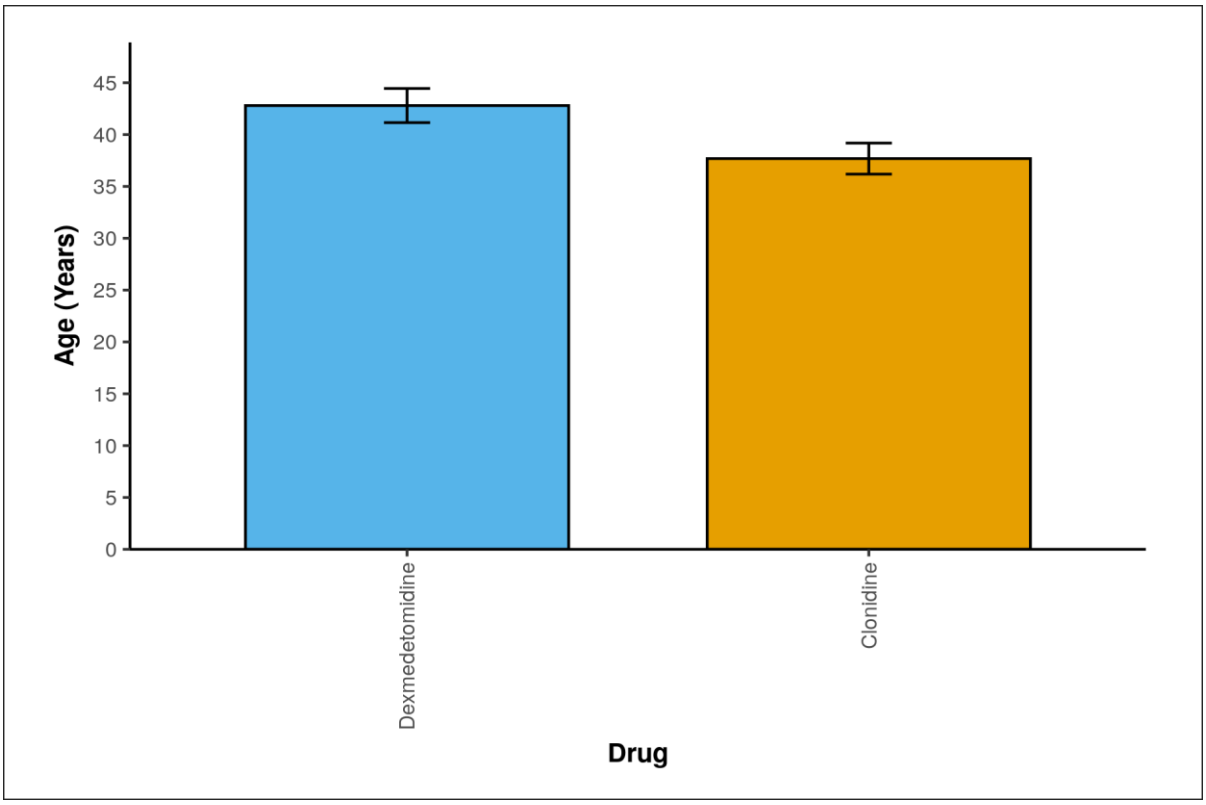

Figure 2: Association Between Drug and Age (Years)

Figure 3 shows - Association between drug and gender

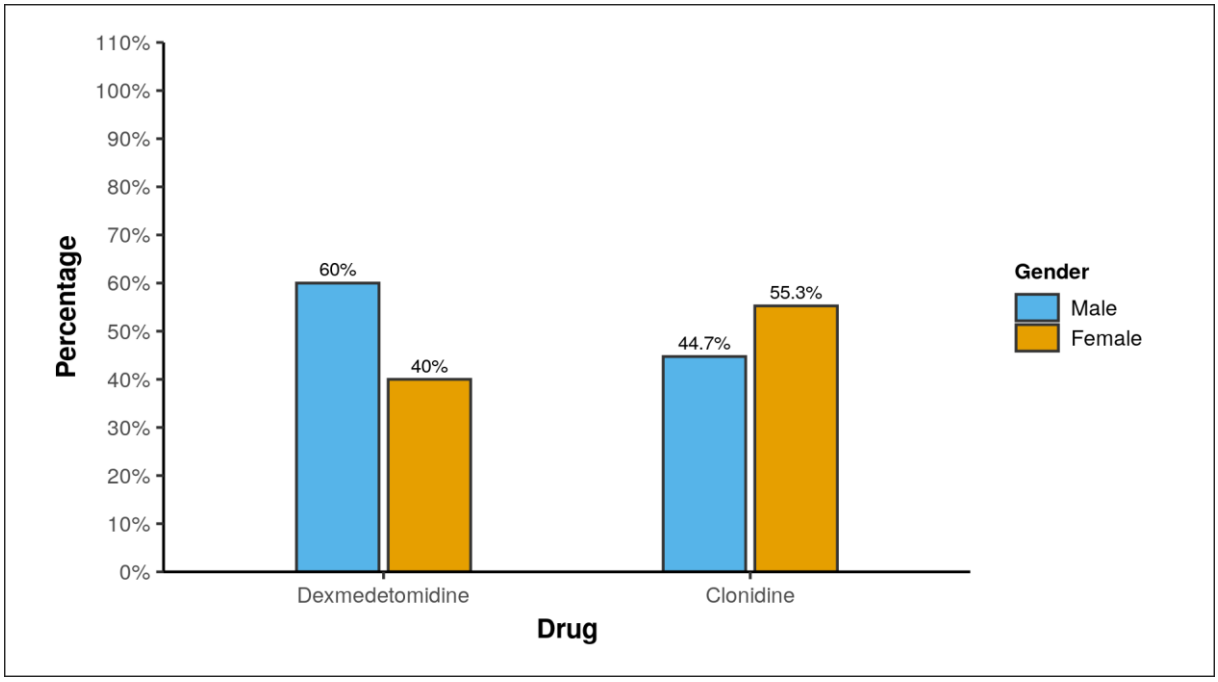

Figure 3: Association between Drug and Gender

Table 2 presents the results of the evaluation of sore throat incidence at various time intervals for two different drugs at various time points

TABLE 2. EVALUATION OF SORE THROAT

Parameters	Drug		p value
	Dexmedetomidine (n = 40)	Clonidine (n = 38)	
Sore Throat (10 Minutes)	0 (0.0%)	1 (2.6%)	0.487[4]
Sore Throat (1 Hour)	1 (2.5%)	4 (10.5%)	0.195[4]
Sore Throat (6 Hours)	5 (12.5%)	19 (50.0%)	<0.001[2]
Sore Throat (12 Hours)	5 (12.5%)	18 (47.4%)	<0.001[2]
Sore Throat (24 Hours)	1 (2.5%)	7 (18.4%)	0.027[4]

2: Chi-Squared Test, 4: Fisher's Exact Test

As depicted in table 2

- At 10 minutes after administration, there was no statistically significant difference (p=0.487) in sore throat incidence between the two drugs, with clonidine showing a slightly higher incidence (2.6%).
- After 1 hour, the incidence of sore throat for clonidine was higher (10.5%) compared to Dexmedetomidine (2.5%), but the difference was not statistically significant (p = 0.1954).
- At 6 hours, there was a significant difference in sore throat incidence between the two drugs. Clonidine resulted in a significantly higher incidence (50.0%) compared to Dexmedetomidine (12.5%) with a p-value < 0.001.
- Similarly, at 12 hours, Clonidine had a significantly higher incidence of sore throat (47.4%) compared to Dexmedetomidine (12.5%), with a p-value < 0.001.
- At 24 hours, the incidence of sore throat with Clonidine (18.4%) was significantly higher than with Dexmedetomidine (2.5%), and this difference was statistically significant with a p-value of 0.0274.
- In summary, the data suggests that Dexmedetomidine may result in a lower incidence of sore throat compared to Clonidine at various time intervals, with statistically significant differences observed at the 6-hour, 12-hour, and 24-hour marks. However, there were no significant differences in sore throat incidence between the two drugs at 10 minutes and 1 hour after administration.

Table 3 shows - Sore throat grades at different time intervals

TABLE 3 SORE THROAT GRADES AT DIFFERENT TIME INTERVAL

Parameters	Drug		p value
	Dexmedetomidine (n = 40)	Clonidine (n = 38)	
Sore Throat Grade (10 Minutes)			
None	40 (100.0%)	37 (97.4%)	0.487[4]
Grade 1	0 (0.0%)	0 (0.0%)	
Grade 2	0 (0.0%)	1 (2.6%)	
Sore Throat Grade (1 Hour)			
None	39 (97.5%)	34 (89.5%).	0.195[4]
Grade 1	1 (2.5%)	4 (10.5%)	
Grade 2	0 (0.0%)	0 (0.0%)	
Sore Throat Grade (6 Hours)			
None	35 (87.5%)	19 (50.0%)	<0.001[4]
Grade 1	4 (10.0%)	12 (31.6%)	
Grade 2	1 (2.5%)	7 (18.4%)	
Sore Throat Grade (12 Hours)			
None	35 (87.5%)	20 (52.6%)	<0.001[4]
Grade 1	4 (10.0%)	18 (47.4%)	
Grade 2	1 (2.5%)	0 (0.0%)	
Sore Throat Grade (24 Hours)			
None	39 (97.5%)	31 (81.6%)	0.005[4]
Grade 1	0 (0.0%)	7 (18.4%)	
Grade 2	1 (2.5%)	0 (0.0%)	

4: Fisher's Exact Test

At 10 minutes postoperatively, only one patient in clonidine group developed grade 2 sore throat and no patient in dexmedetomidine group developed sore throat (p=0.487).

At 1hour postoperatively, four patients in clonidine group had grade 1 sore throat and one patient in dexmedetomidine group developed grade 1 sore throat (p=0.195).

At 6 hours postoperatively, twelve patients in clonidine group had grade 1 sore throat and four patients in dexmedetomidine group developed grade 1 sore throat. Whereas, seven patients in

clonidine group developed grade 2 sore throat and one patient in dexmedetomidine group developed grade 2 sore throat ($p<0.001$).

At 12 hours postoperatively, 18 patients in clonidine group had grade 1 sore throat and four patients in dexmedetomidine group developed grade 1 sore throat ($p<0.001$). Whereas, one patient in dexmedetomidine group developed grade 2 sore throat.

At 24 hours postoperatively, seven patients in clonidine group had grade 1 sore throat and one patient in dexmedetomidine group developed grade 2 sore throat ($p=0.005$).

Table 4 shows - Comparison of heart rate at different time interval in two groups

TABLE 4. COMPARISON OF HEART RATE AT DIFFERENT POINT INTERVAL

Parameters	Drug		p value
	Dexmedetomidine (n = 40)	Clonidine (n = 38)	
Heart Rate (BPM) (Baseline)	81.88 ± 12.70	81.11 ± 14.41	0.406[3]
Heart Rate (BPM) (Induction)	82.28 ± 12.25	80.87 ± 9.26	0.638[3]
Heart Rate (BPM) (Laryngoscopy)	85.90 ± 10.25	84.84 ± 7.30	0.600[1]
Heart Rate (BPM) (Intubation)	87.10 ± 12.22	84.61 ± 7.88	0.285[1]
Heart Rate (BPM) (1 Minute After Intubation)	80.03 ± 8.87	77.95 ± 9.26	0.315[1]
Heart Rate (BPM) (5 Minute After Intubation)	75.67 ± 10.53	75.11 ± 12.11	0.309[3]
Heart Rate (BPM) (After Extubation)	78.95 ± 14.81	77.95 ± 11.68	0.916[3]

1: t-test, 3: Wilcoxon-Mann-Whitney U Test,

There was no significant difference in the trend of heart rate at any of the time points in both the groups.

Figure 4 shows - A line diagram depicting the change in Heart Rate over time points in the two groups.

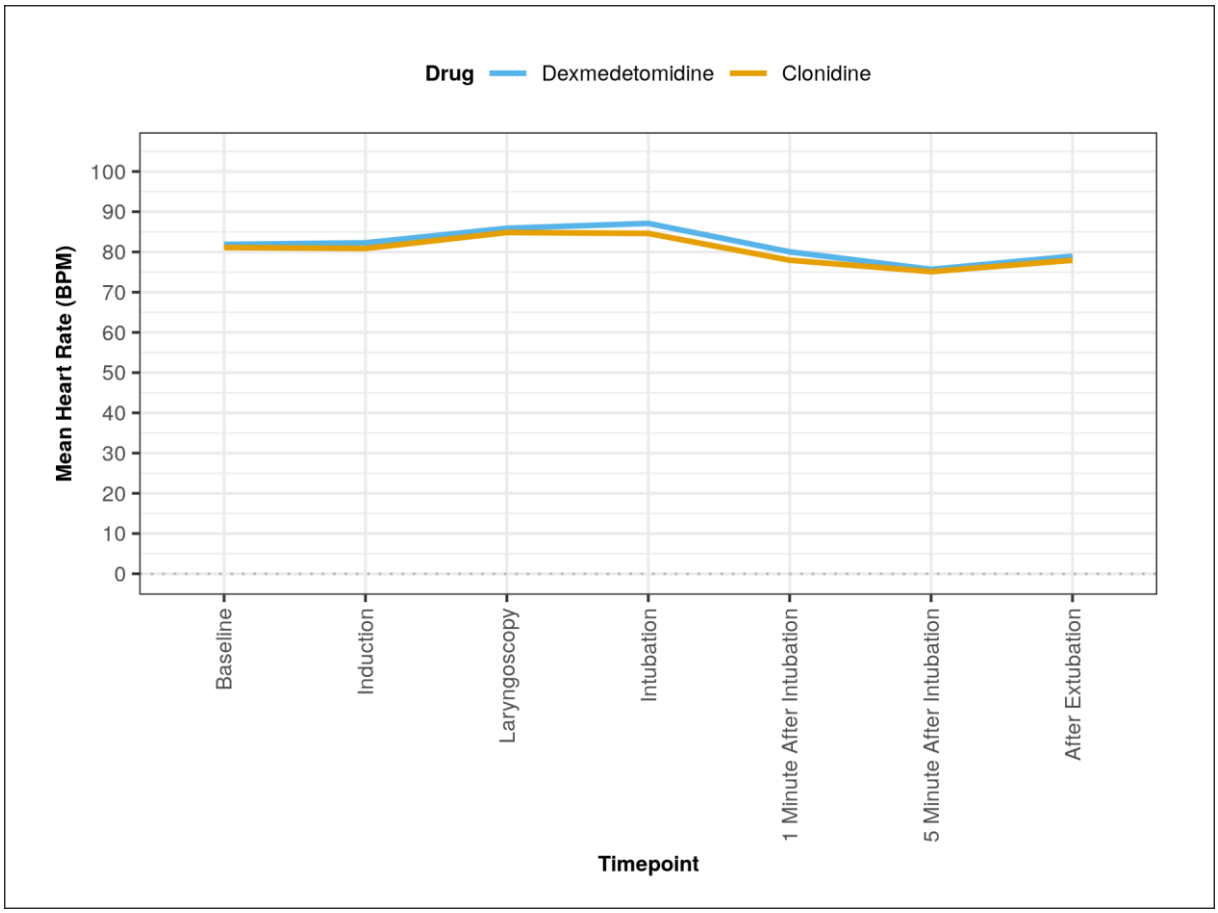

Figure 4: Change in Heart Rate (BPM) Over Time

Table 5 - Depicts comparison of SBP at different time intervals in two groups.

TABLE 5. COMPARISON OF SBP AT DIFFERENT TIME INTERVAL

Parameters	Drug		p value
	Dexmedetomidine (n = 40)	Clonidine (n = 38)	
Systolic BP (mmHg) (Baseline)	130.98 ± 12.83	126.34 ± 9.17	0.070[1]
Systolic BP (mmHg) (Induction)	118.62 ± 15.01	115.50 ± 14.75	0.357[1]
Systolic BP (mmHg) (Laryngoscopy)	123.88 ± 13.90	122.11 ± 16.31	0.6523
Systolic BP (mmHg) (Intubation)	117.17 ± 19.83	126.79 ± 10.95	0.098[3]
Systolic BP (mmHg) (1 Minute After Intubation)	109.17 ± 16.27	109.68 ± 14.56	0.884[1]
Systolic BP (mmHg) (5 Minute After Intubation)	116.83 ± 12.61	108.24 ± 12.01	0.0023
Systolic BP (mmHg) (After Extubation)	119.42 ± 12.59	123.13 ± 11.24	0.261[3]

1: t-test, 3: Wilcoxon-Mann-Whitney U Test

The overall change in systolic blood pressure over different time points was comparable in the two groups except at 5 minutes after intubation when it was statistically significant (p= 0.0023).

In figure 5 - Depicting the change in systolic blood pressure over time in the two groups.

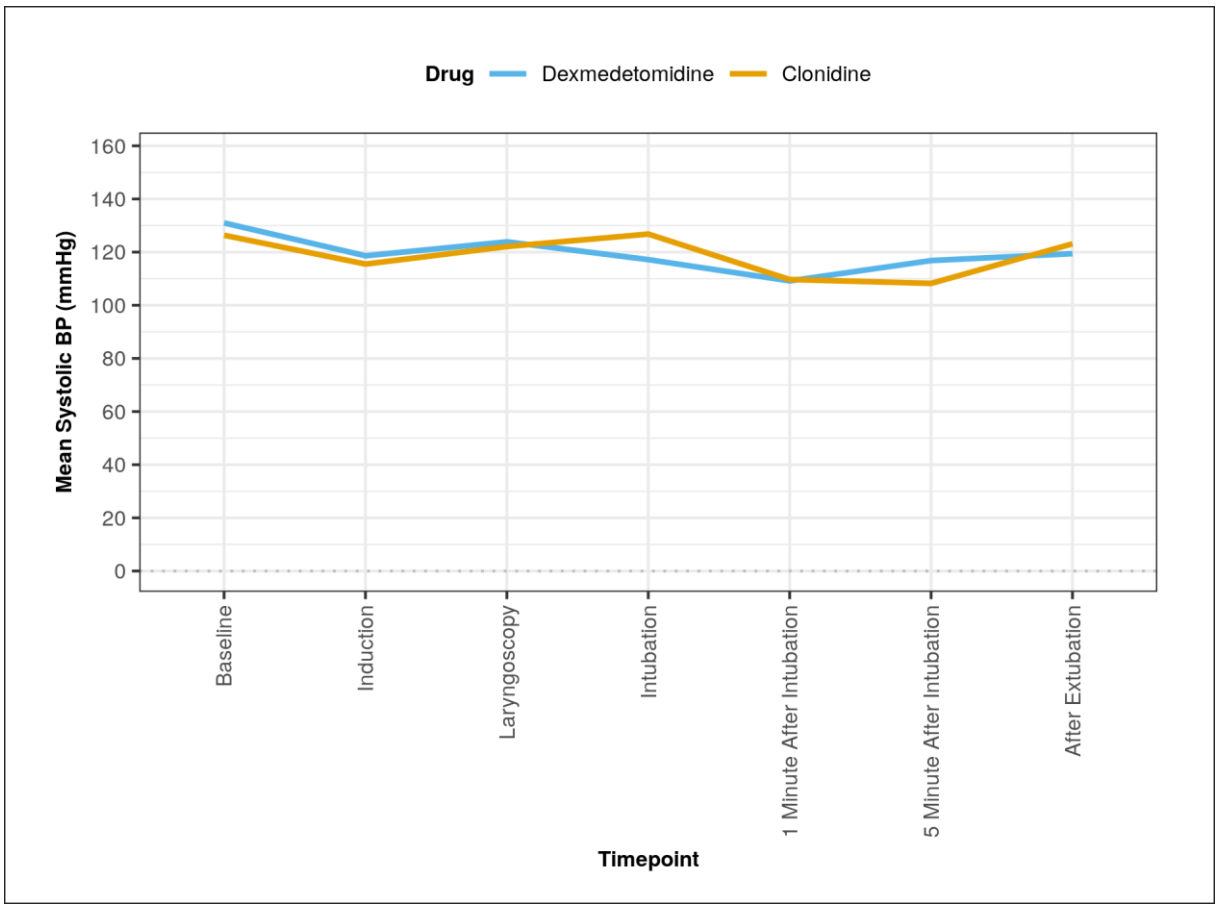

Figure 5: Change in Systolic BP (mmHg) Over Time

Table 6 – Depicts comparison of DBP at different time interval

TABLE 6. COMPARISON OF DBP AT DIFFERENT TIME INTERVAL

Parameters	Drug		p value
	Dexmedetomidine (n = 40)	Clonidine (n = 38)	
Diastolic BP (mmHg) (Baseline)	82.17 ± 9.96	79.05 ± 6.45	0.078[1]
Diastolic BP (mmHg) (Induction)	71.97 ± 12.34	72.74 ± 12.05	0.783[1]
Diastolic BP (mmHg) (Laryngoscopy)	75.62 ± 14.69	77.55 ± 14.13	0.631[3]
Diastolic BP (mmHg) (Intubation)	71.42 ± 15.59	81.13 ± 13.06	0.004[1]
Diastolic BP (mmHg) (1 Minute After Intubation)	65.10 ± 9.90	67.21 ± 10.77	0.371[1]
Diastolic BP (mmHg) (5 Minute After Intubation)* **	72.95 ± 14.44	65.84 ± 9.24	0.020[3]
Diastolic BP (mmHg) (After Extubation)	75.60 ± 12.77	74.68 ± 10.32	0.972[3]

1: t-test, 3: Wilcoxon-Mann-Whitney U Test,

The overall change in diastolic BP (mmHg) over time was comparable in the two groups except at the time of intubation and 5 minutes after intubation when it was statistically significant.

Figure 6 shows a diagram depicting the change in diastolic blood pressure over time in the two groups.

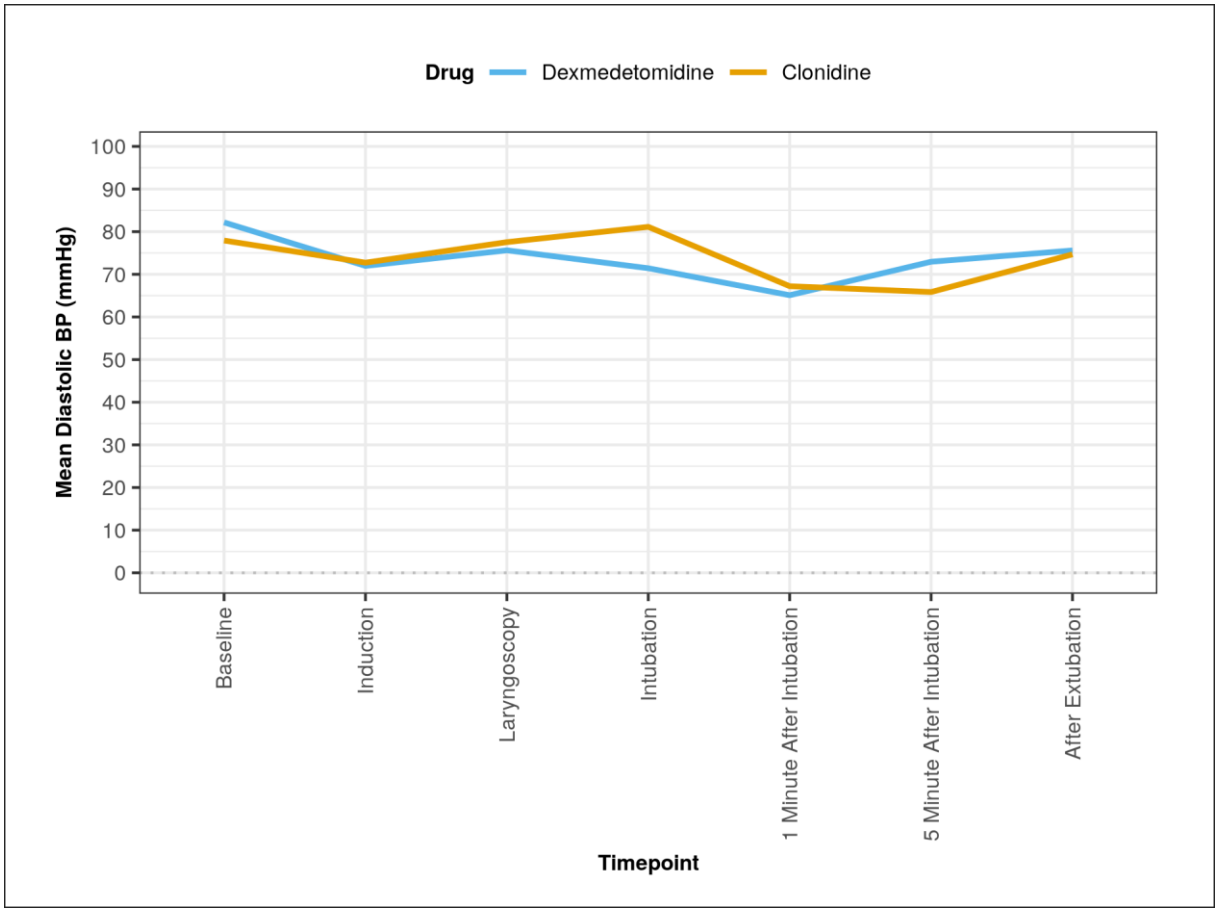

Figure 6: Change in Diastolic BP (mmHg) over time

Table 7 - Depicts comparison of MAP at different time interval.

TABLE 7. COMPARISON OF MAP AT DIFFERENT TIME INTERVAL

Parameters	Drug		p value
	Dexmedetomidine (n = 40)	Clonidine (n = 38)	
MAP (mmHg) (Baseline)	98.58 ± 10.41	95.05 ± 9.99	0.09[1]
MAP (mmHg) (Induction)	89.10 ± 12.66	85.53 ± 12.48	0.2131
MAP (mmHg) (Laryngoscopy)	89.55 ± 13.73	89.82 ± 14.87	0.9351
MAP (mmHg) (Intubation)	86.28 ± 16.98	96.13 ± 18.98	0.0323
MAP (mmHg) (1 Minute After Intubation)	79.12 ± 11.12	80.47 ± 10.98	0.7383
MAP (mmHg) (5 Minute After Intubation)	84.00 ± 12.31	79.84 ± 9.61	0.1001
MAP (mmHg) (After Extubation)	88.15 ± 11.07	86.32 ± 11.02	0.466[1]

1: t-test

The overall change in mean arterial pressure over time was comparable in the two groups except at the time of intubation when it was statistically significant ($p<0.05$).

Figure 7 shows - Diagram depicting the change in MAP (mmHg) over time in the two groups.

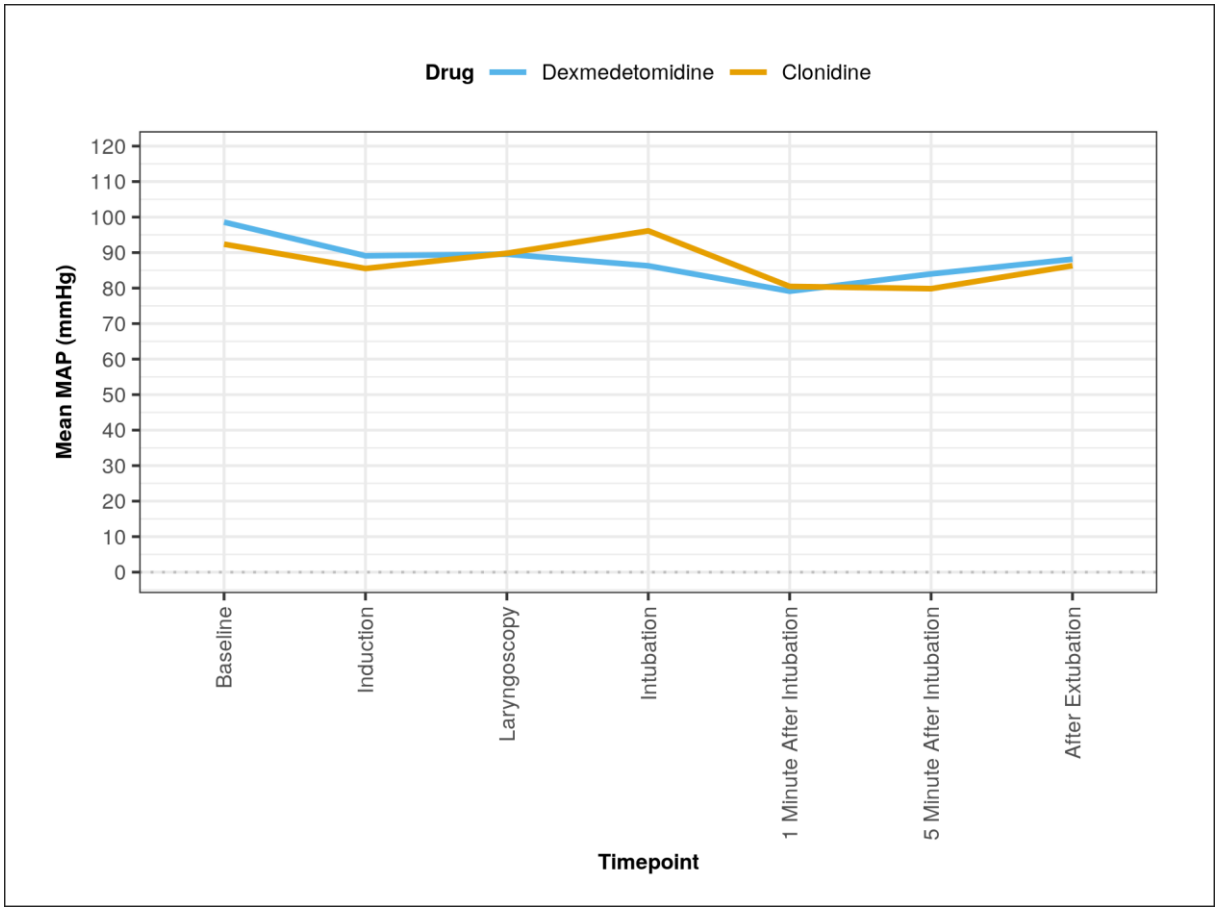

Figure 7: Change in MAP (mmHg) Over Time

TABLE 8. ETT INTRA CUFF PRESSURE AT DIFFERENT POINT INTERVAL

Parameters	Drug		p value
	Dexmedetomidine (n = 40)	Clonidine (n = 38)	
ETT Intra Cuff Pressure (Intubation)	28.87 ± 3.92	28.23 ± 4.70	0.104[1]
ETT Intra Cuff Pressure (During Gas Insufflation Of Abdomen)	28.52 ± 5.37	28.42 ± 6.18	0.860[3]
ETT Intra Cuff Pressure (Extubation)	27.85 ± 4.49	27.94 ± 6.15	0.208[1]

1: t-test, 3: Wilcoxon-Mann-Whitney U Test

The overall change in ETT Intra Cuff Pressure over time was comparable in the two groups as shown in table 8.

TABLE 9. AIRWAY PRESSURE AT DIFFERENT POINT INTERVAL

Parameters	Drug		p value
	Dexmedetomidine (n = 40)	Clonidine (n = 38)	
Airway Pressure (Intubation)	17.38 ± 3.15	17.05 ± 1.95	0.062[3]
Airway Pressure (During Gas Insufflation Of Abdomen)	22.32 ± 3.18	21.47 ± 2.38	0.1723
Airway Pressure (Extubation)	17.48 ± 2.46	16.89 ± 2.93	0.152[3]

3: Wilcoxon-Mann-Whitney U Test

The overall change in airway pressure over different time points were comparable in the two groups as shown in table 9.

DISCUSSION

The primary objective of this study was to compare the efficacy of ultrasonic nebulization with dexmedetomidine and clonidine on post- operative sore throat in patients undergoing elective laparoscopy cholecystectomy under general anesthesia with endotracheal tube.

We found that sore throat was more observed in the patients nebulized with clonidine as compared to dexmedetomidine which was more evident at 6h, 12h and 24 h after surgery.

The secondary objective of the study was to estimate the effect of ultrasonic nebulization with dexmedetomidine and clonidine on hemodynamic stability during laryngoscopy and intubation in patients undergoing laparoscopy cholecystectomy.

We found that there was no significant difference in the trend of heart rate at any of the time points in both the groups. The overall change in systolic blood pressure over different time points was comparable in the two groups except at 5 minutes after intubation when it was statistically significant ($p= 0.0023$). The overall change in diastolic BP over time was comparable in the two groups except at the time of intubation and 5 minutes after intubation when it was statistically significant. The overall change in mean arterial pressure over time was comparable in the two groups except at the time of intubation when it was statistically significant ($p<0.05$). The primary objective of this study was to compare the efficacy of ultrasonic nebulization with dexmedetomidine and clonidine on post- operative sore throat in patients undergoing elective laparoscopy cholecystectomy under general anesthesia with endotracheal tube.

We found that sore throat was more observed in the patients nebulized with clonidine as compared to dexmedetomidine which was more evident at 6h, 12h and 24 h after surgery.

The secondary objective of the study was to estimate the effect of ultrasonic nebulization with dexmedetomidine and clonidine on hemodynamic stability during laryngoscopy and intubation in patients undergoing laparoscopy cholecystectomy.

Several factors have been identified in earlier studies contributing to sore throat after surgery, including patient's age, sex, cuff design, intracuff pressure, and tracheal tube size. (32) However, in the present study, all these variables were found to be comparable.

In the previous studies incidence of the POST varies from18–74% (1) (2) (5) (25) Whereas, the overall incidence of POST in the present study is 1.2 % at 10 minutes, 6.4 % at 1 hour, 30 % at 6 hours, 29 % at 12 hours and 10 % at 24 hours, which is similar to previous studies.

The lesser incidence and lesser severity of POST in the dexmedetomidine group in comparison to the clonidine group may be supported by multifaceted protective functions of dexmedetomidine. The significant decline in the incidence and severity of POST that we noted in our dexmedetomidine group can be attributed to the significant reduction in the inflammatory mediator caused by nebulised dexmedetomidine when administered pre-operatively, along with its analgesic action.

Dexmedetomidine selectively activates α2-adrenaline receptors in the locus coeruleus and is a derivative of medetomidine, which inhibits the sympathetic nervous system and reduces the release of norepinephrine. (33)

Dexmedetomidine is proved to reduce the pro-inflammatory cytokine production, attenuates the inflammatory response and inhibits pain signals. (34)(35)(36) (37)

Zhang and Zhang (38) found that dexmedetomidine decreases the serum level of inflammatory mediators like TNF-α, IL-6 and S100β and hence providing neuroprotection by decreasing the incidence of cerebral injury in patients undergoing cardiac valve replacement.

Zhu H, (39) in his study also concluded that dexmedetomidine has anti-inflammatory action in patients undergoing one lung ventilation.

Liu Y *et al* (40) conducted a metanalysis, which included 400 patients and evaluated the effect of intravenous dexmedetomidine on POST, and found that dexmedetomidine significantly reduced the incidence of POST.

Iirola *et al.* (14) in their study compare the pharmacokinetic and pharmacodynamic properties of intranasal and intravenous mode of administration and concluded that pharmacological effects were similar with both routes of administration. Nebulizations would act more locally at the desired site, and also are, likely to have a much lower concentration in the blood, hence containing the possible systemic adversities.

Thomas D *et al.* (1) in their study while comparing dexmedetomidine nebulization with ketamine nebulization preoperatively found that dexmedetomidine nebulization is safe method in attenuating POST, with less hemodynamic derangements.

Hyuckgoo Kim *et al* (21) in their study inferred that dexmedetomidine infusion is effective in reducing the incidence and severity of POST for 24 h after thyroidectomy.

One recent study by Satyajeet Misra *et al* (22), shows that preoperative dexmedetomidine nebulization has no effect on the POST, although the intraoperative anesthetic and analgesic consumption was found to be less.

Unfortunately, there is no study regarding use of clonidine nebulization preoperatively to assess POST although in one study Shekhar S *et al* (13) compare the effect of ketamine nebulization with ketamine and clonidine nebulization and found that ketamine plus clonidine preoperatively is more effective in reducing POST with no adverse effects as compared to preoperative nebulization with ketamine.

Clonidine is a non –selective alpha 2 adrenergic receptor agonist that selectively stimulates post synaptic alpha-adrenergic receptors in the depressor site of vasomotor centre of the medulla oblongata in the region of the nucleus of the solitary tract or locus coeruleus.

Central alpha-adrenergic receptors weaken the vasoconstrictive tone of efferent sympathetic neurons in the heart, kidneys and peripheral vessels, causing vasodilation and lowering blood pressure. Many studies show that clonidine causes allergic reactions to analgesics regardless of the route of administration (central or peripheral).

Local application of clonidine induces analgesia by blocking the pain-induced peripheral terminals of α2-adrenergic receptors without causing administration-related side effects. (16) (17) (18) (19) (20)

The overall change in systolic blood pressure over different time points was comparable in the two groups except at 5 minutes after intubation when it was statistically significant (p= 0.0023). The overall change in diastolic blood pressure over time was comparable in the two groups except at the time of intubation and 5 minutes after intubation when it was statistically significant. The overall change in mean arterial pressure over time was comparable in the two groups except at the time of intubation and 5 minutes after intubation when it was statistically significant ($p<0.05$).

Sanjay Kumar Gupta *et al* (41) conducted a study to compare dexmedetomidine and clonidine for attenuation of hemodynamic response during laryngoscopy and intubation.

They observed that premedication with intravenous clonidine blunts the stress response to surgical stimuli. Clonidine increases the cardiac baroreceptor reflex sensitivity to increase systolic blood pressure and hence stabilizes blood pressure. Which also supports our finding that there was overall decrease in all the study parameters in clonidine and decrease in diastolic blood pressure and mean arterial blood pressure at baseline and 5 minutes after intubation in clonidine.

Various studies have investigated the effects of intravenous dexmedetomidine on the hemodynamic response to laryngoscopy and intubation. Our results differ from those of previous studies. (9) (10) Although we found that the increase in heart rate was not significant in both the

groups, there was no significant difference in the SBP increases following induction and laryngoscopy. This may be explained by our different route of administration. In this study mode of administration was nebulization instead of intravenous hence the bioavailability might differ in both mode of administration.

None of the patients in our study who received dexmedetomidine and clonidine nebulization had any side effects such as bradycardia, hypotension or cough. Also, no patient experienced coughing or bucking on extubation.

Increased endotracheal tube intracuff pressure is suggested as one of the risk factor for POST. (25) In our study endotracheal tube intracuff pressure is comparable in dexmedetomidine and clonidine group.

SUMMARY

The present study is a prospective observational study, conducted in department of anaesthesiology for a time period of 18 month. This study evaluates and compares the effect of ultrasonically nebulised dexmedetomidine and clonidine on the post-operative sore throat in patients undergoing elective laparoscopy cholecystectomy under general anesthesia with endotracheal tube.

The primary objective of this study was to estimate and compare the efficacy of these two drugs on post- operative sore throat at 10 minutes, 1 hour, 6 hour, 12 hour and 24 hour after extubation whereas the secondary objective was to estimate and compare the effect of these two drugs on hemodynamic stability at baseline, at induction, at laryngoscopy, at intubation, 1min after intubation and 5 min after intubation and after extubation.

We found that incidence and severity of post-operative sore throat was more observed in the patients nebulized with clonidine as compared to dexmedetomidine which was more evident at 6h, 12h and 24 h after surgery. Hemodynamics was comparable in term of heart rate, and most of the time points in terms of systolic blood pressure, diastolic blood pressure and mean arterial blood pressure.

The incidence of postoperative sore throat in the present study is 1.2 % at 10 minutes after extubation, 6.4 % at 1 hour after extubation, 30 % at 6 hours after extubation, 29 % at 12 hours after extubation and 10 % at 24 hours after extubation.

This study concludes that, preoperative ultrasonic Nebulization with dexmedetomidine is more effective in reducing incidence and severity of postoperative sore throat when compared to clonidine. Randomized control trial with larger sample size including higher risk group are further needed to compare the effect of nebulised dexmedetomidine and clonidine on post-operative sore throat.

STRENGTH AND LIMITATIONS

The main strength of our study is that, there is literature deficit as no any previous study compares the effect of ultrasonically nebulised dexmedetomidine and clonidine on the postoperative sore throat. The limitations of this study need to be addressed. This is a non-randomized study so the chance of biased is the possibility, however we did our best to avoid the bias. Only ASAI and ASA II patients were recruited and high-risk patients with comorbidities were not included. We didn't include measurement of plasma dexmedetomidine or clonidine levels during the study and no formal sedation scale was used. Lastly, we can't rule out contribution of the systemic effect of the study drugs.

CONCLUSION

This study concludes that, the preoperative ultrasonic Nebulization with dexmedetomidine is more effective in reducing incidence and severity of postoperative sore throat when compared to clonidine in patients undergoing elective laparoscopic cholecystectomy under general anaesthesia with endotracheal tube.

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ANNEXURES I: PROFORMA

CASE NO: Date:

Name: UHID No.: Age/Sex:

Weight / Height:

Diagnosis: …….

Operation: ……..

In time: ……. Out-time: ……..

Vitals:

Time	Heart Rate	Systolic BP	Diastolic BP	Mean BP	SpO2
Baseline					
at induction					
At laryngoscopy					
At intubation					
1 minute after intubation					
5 minutes after intubation					
After extubation					

	Intubation	During gas insufflation of abdomen	extubation
Airway pressure			
Intra- abdominal pressure			
ET tube intra cuff pressure			

Drug given:

Evaluation of sore throat after extubation:

	0	1	2	3
10 minutes				
1hr				
6hr				
12hr				
24 hr				

ANNEXURE II **:PARTICIPANT INFORMATION SHEET**

Dear Patient...

We are conducting an observational study at the All India Institute of Medical Sciences, Bhopal to evaluate the effect of ultrasonic nebulisation with dexmedetomidine and clonidine on post- operative sore throat in patients undergoing elective laparoscopic cholecystectomy under general endotracheal anaesthesia.

Patient is invited to take part in the study. You are requested to go through the following paragraphs:

i) **Title of the study:** "Comparison of ultrasonic nebulisation with dexmedetomidine versus clonidine for post-operative sore throat- A prospective, observational Study

ii) **Purpose of the study**: The aim of our study is to compare ultrasonic nebulisation with dexmedetomidine versus clonidine for post- operative sore throat in laparoscopic cholecystectomy surgeries being performed at AIIMS, Bhopal.

iii) **Methodology**: A standard anaesthetic technique will be followed in all the patients included in the study. Written informed consent and thorough pre-anaesthetic evaluation will be done prior to recruiting patients. Patients undergoing laparoscopic cholecystectomy surgeries who require an endotracheal tube to be placed will be recruited. A dose of 50mcg dexmedetomidine and 100 mcg of clonidine diluted in 4ml normal saline will be used for the purpose. Nebulisation will be done by an ultrasonic nebuliser (Sahyog Wellness Ultrasonic Nebuliser Machine (MY-520A) with the help of a wall attached oxygen drive source 15 minutes prior to inducing the patient for 15 minutes.

iv) **Eligibility to participate in the study**: All patients aged 18-65years with undergoing head and laparoscopic cholecystectomy surgeries are eligible to participate in the study.

v) **Any risk to the subject associated with the study**: As this is a purely an observational study with no alteration of standard perioperative management, there is no identified risk associated with this study.

vi) **Confidentiality**: All the records will be confidential and the patient identity would be known to the chief investigator and would not be released to anybody else.

vii) **Provision of free treatment for research related injury**: No research related injury is expected and if any complication occurs, then participants are not liable for any compensation.

viii) **Freedom of individual to participate and to withdraw from research at any time without penalty or loss of benefits to which the subject would otherwise entitled:**

Participation in the study is purely voluntary. Refusal to participate will not influence care of the participants in this hospital in any way.

ix) **Costs and Source of investigations and drugs**: You will not be charged for anything related to this study project.

x) **Benefits:** There is no direct benefit for you from this study.

xi) **Available information sources:** The study is approved by the institute human ethics review board, AIIMS, Bhopal. Any query regarding the study can be clarified by contacting Dr.Vandana mehra (phone: 9131718921), principal investigator of the study.

All this information will be confidential and will not be disclosed to anybody.

Contact details of the ethics committee:

Dr. Shashank Purwar (Study independent person)

Member secretary,

IHEC,

AIIMS, Bhopal

Email: ihec@aiimsbhopal.edu.in

Contact no. 07773010099

ANNEXURE:III

रोगी सूचना पत्र

प्रिय रोगी...

हम अखिल भारतीय आयुर्विज्ञान संस्थान, भोपाल में एक अवलोकन अध्ययन कर रहे हैं ऑपरेशन के बाद गले में खराश के लिए डेक्समेडेटोमिडाइन बनाम क्लोनिडाइन के साथ अल्ट्रासोनिक नेबुलाइजेशन की तुलना- एक संभावित अवलोकन संबंधी अध्ययन

आपसे अनुरोध है कि के माध्यम से जाएं निम्नलिखित पैराग्राफ:

i) अध्ययन का शीर्षक: "अल्ट्रासोनिक नेबुलाइजेशन की तुलना डेक्समेडेटोमिडाइन बनाम क्लोनिडाइन के साथ ऑपरेशन के बाद गले में खराश के लिए- एक संभावित, अवलोकन संबंधी अध्ययन|

ii) अध्ययन का उद्देश्य: हमारे अध्ययन का उद्देश्य एम्स, भोपाल में की जा रही लैप्रोस्कोपिक कोलेसिस्टेक्टोमी सर्जरी में ऑपरेशन के बाद गले में खराश के लिए डेक्समेडिटोमिडाइन बनाम क्लोनिडाइन के साथ अल्ट्रासोनिक नेबुलाइजेशन की तुलना करना है|

iii) कार्यप्रणाली: अध्ययन में शामिल सभी रोगियों में एक मानक संवेदनाहारी तकनीक का पालन किया जाएगा। रोगियों को भर्ती करने से पहले लिखित सूचित सहमति और संपूर्ण पूर्व-संवेदनाहारी मूल्यांकन किया जाएगा। लैप्रोस्कोपिक कोलेसिस्टेक्टोमी सर्जरी से गुजरने वाले मरीजों को भर्ती किया जाएगा, जिन्हें एंडोट्रैचियल ट्यूब लगाने की आवश्यकता होती है। 50 एमसीजी डेक्समेडेटोमिडाइन की एक खुराक और 100 एमसीजी क्लोनिडाइन को 4 मिली सामान्य सेलाइन में पतला करके इस उद्देश्य के लिए उपयोग किया जाएगा। रोगी को 15 मिनट के लिए प्रेरित करने से 15 मिनट पहले दीवार से जुड़े ऑक्सीजन ड्राइव स्रोत की मदद से एक अल्ट्रासोनिक नेबुलाइज़र (सहयोग वेलनेस अल्ट्रासोनिक नेबुलाइज़र मशीन (MY-520A)) द्वारा नेबुलाइज़ेशन किया जाएगा।

iv) अध्ययन में भाग लेने की पात्रता: लेप्रोस्कोपिक कोलेसिस्टेक्टोमी सर्जरी वाले 18-65 वर्ष की आयु के सभी रोगी अध्ययन में भाग लेने के पात्र हैं।

v) अध्ययन से जुड़े विषय के लिए कोई जोखिम: चूंकि यह मानक पेरिऑपरेटिव प्रबंधन में कोई परिवर्तन नहीं होने के साथ एक विशुद्ध रूप से एक अवलोकन अध्ययन है, इसलिए इस अध्ययन से जुड़ा कोई पहचाना जोखिम नहीं है ।

vi) गोपनीयता: सभी रिकॉर्ड गोपनीय होंगे और रोगी की पहचान मुख्य अन्वेषक को पता चल जाएगी और किसी और को जारी नहीं किया जाएगा ।

vii) अनुसंधान से संबंधित चोट के लिए मुफ्त उपचार का प्रावधान: कोई अनुसंधान से संबंधित चोट नहीं है अपेक्षित है और यदि कोई जटिलता होती है, तो प्रतिभागी किसी भी मुआवजे के लिए उत्तरदायी नहीं हैं।

viii) व्यक्ति की स्वतंत्रता में भाग लेने के लिए और दंड या लाभ की हानि है जो विषय अंयथा हकदार होगा बिना किसी भी समय अनुसंधान से वापस लेने के लिए: अध्ययन में भागीदारी विशुद्ध रूप से स्वैच्छिक है । भाग लेने से इनकार किसी भी तरह से इस अस्पताल में प्रतिभागियों की देखभाल को प्रभावित नहीं करेगा ।

ix) लागत और जांच और दवाओं के स्रोत: आप इस अध्ययन परियोजना से संबंधित कुछ के लिए शुल्क नहीं लिया जाएगा ।

x) लाभ: इस अध्ययन से आपके लिए कोई सीधा लाभ नहीं है।

xi) उपलब्ध जानकारी सूत्रों: अध्ययन संस्थान मानव नैतिकता समीक्षा बोर्ड, एम्स, भोपाल द्वारा अनुमोदित है । अध्ययन के संबंध में किसी भी प्रश्न को अध्ययन की प्रमुख अन्वेषक डॉ वंदना (फोन: 9131718921) से संपर्क करके स्पष्ट किया जा सकता है ।

यह सारी जानकारी गोपनीय होगी और इसका खुलासा किसी को नहीं किया जाएगा।

आचार समिति के संपर्क विवरण:

डॉ शशांक पुरवर (अध्ययन स्वतंत्र व्यक्ति)
सदस्य सचिव,
आई एच ई सी,
एम्स, भोपाल
ईमेल: ihec@aiimsbhopal.edu.in
संपर्क संख्या: 07773010099

ANNEXURE: IV INFORMED CONSENT

Title: Comparison of ultrasonic nebulisation with dexmedetomidine versus clonidine for post-operative sore throat- A prospective observational study.

1. I confirm that I have read and understood the patient information sheet for the study. I confirm that the study has been explained to me and I have had ample time and opportunity to ask questions.	[ ]
2. I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.	[ ]
3. I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s)	[ ]

I confirm that I have fully explained all aspects of the trial to the subject (or legally acceptable representative)

Signature of the person conducting the Informed Consent

_____	_____	___/___/_____
Name of the Study Investigator	Signature of the Study Investigator	Date Month Year

Name of the participant

Signature of the participant

ANNEXURE 5: **सूचित सहमति प्रपत्र**

ऑपरेशन के बाद गले में खराश के लिए डेक्समेडेटोमिडाइन बनाम क्लोनिडाइन के साथ अल्ट्रासोनिक नेबुलाइजेशन की तुलना- एक संभावित अवलोकन संबंधी अध्ययन

1. मैं पुष्टि करता हूं कि मैंने अध्ययन के लिए रोगी सूचना पत्र को पढ़ा और समझा है। मैं इस बात की पुष्टि करता हूं कि अध्ययन मुझे समझाया गया है और मुझे प्रश्न पूछने के लिए पर्याप्त समय और अवसर मिला है ।	[ ]
2. मैं समझता हूं कि अध्ययन में मेरी भागीदारी स्वैच्छिक है और मैं किसी भी समय वापस लेने के लिए स्वतंत्र हूं, किसी भी कारण दिए बिना, मेरी चिकित्सा देखभाल या कानूनी अधिकारों को प्रभावित किया जा रहा बिना ।	[ ]
3. मैं इस अध्ययन से उत्पन्न होने वाले किसी भी डेटा या परिणामों के उपयोग को प्रतिबंधित नहीं करने के लिए सहमत हूं बशर्ते ऐसा उपयोग केवल वैज्ञानिक उद्देश्य के लिए हो (ओं)	[ ]

मैं पुष्टि करता हूं कि मैंने इस विषय पर परीक्षण के सभी पहलुओं को पूरी तरह से समझाया है (या कानूनी रूप से स्वीकार्य प्रतिनिधि)
सूचित सहमति का संचालन करने वाले व्यक्ति के हस्ताक्षर

_____	_____	____/___/_____
अध्ययन अन्वेषक का नाम	अध्ययन अन्वेषक के हस्ताक्षर	तिथि माह वर्ष

प्रतिभागी का नाम _____ प्रतिभागी के हस्ताक्षर

MASTER CHART

S.no	Age	Sex	Diagnosis	Operation	Duration	Drug given	HR	SBP	BASELINE DBP
1	30	F	cholelithiasis	lap cholecystectomy	160min	DEXMEDETOMIDINE	88	137	68
2	27	F	cholelithiasis	lap cholecystectomy	130 min	CLONIDINE	111	112	80
3	29	F	cholelithiasis	lap cholecystectomy	200 min	CLONIDINE	72	138	80
4	57	F	cholelithiasis	lap cholecystectomy	150 min	DEXMEDETOMIDINE	99	139	96
5	39	F	cholelithiasis	lap cholecystectomy	130 min	DEXMEDETOMIDINE	92	113	75
6	52	M	cholelithiasis	lap cholecystectomy	150 min	DEXMEDETOMIDINE	72	164	91
7	37	F	resolved gallstone induced pancreatitis	lap cholecystectomy	200 min	CLONIDINE	80	115	80
8	52	F	cholelithiasis with sealed GB perforation	lap cholecystectomy	200 min	DEXMEDETOMIDINE	63	143	92
9	30	M	gall stone disease	lap cholecystectomy	180 min	DEXMEDETOMIDINE	78	138	69
10	58	F	cholelithiasis	lap cholecystectomy	160 min	CLONIDINE	85	132	82
11	42	M	Cholelithiasis	lap cholecystectomy	110 min	CLONIDINE	62	127	82
12	32	M	Cholelithiasis	lap cholecystectomy	200 min	DEXMEDETOMIDINE	70	111	66
13	25	F	Cholelithiasis	lap cholecystectomy	90 min	DEXMEDETOMIDINE	92	107	77
14	32	M	gall stone disease	lap cholecystectomy	120 min	CLONIDINE	72	118	75
15	48	F	gall stone disease	lap cholecystectomy	150 min	DEXMEDETOMIDINE	68	132	84
16	38	F	gall stone disease	lap cholecystectomy	200 min	DEXMEDETOMIDINE	92	124	94
17	47	F	gall stone disease	lap cholecystectomy	180min	CLONIDINE	69	139	75
18	32	M	Cholelithiasis	lap cholecystectomy	100min	CLONIDINE	77	130	74
19	36	M	Cholelithiasis	lap cholecystectomy	210min	CLONIDINE	89	110	82
20	60	M	gall stone disease	lap cholecystectomy	100min	DEXMEDETOMIDINE	78	137	90
21	43	F	cholelithiasis	lap cholecystectomy	120min	CLONIDINE	92	131	82
22	31	M	cholelithiasis	Lap cholecystectomy	150min	DEXMEDETOMIDINE	75	135	90
23	30	F	cholelithiasis	lap cholecystectomy	150min	DEXMEDETOMIDINE	133	114	70
24	38	F	cholecystitis	lap cholecystectomy	110min	DEXMEDETOMIDINE	84	120	83
25	52	M	Cholelithasis	lap cholecystectomy	120min	CLONIDINE	65	120	78
26	55	F	gall stone disease	lap cholecystectomy	180min	DEXMEDETOMIDINE	61	128	75
27	35	M	resolved acute cholecystitis with cholelithiasis	lap cholecystectomy	130min	CLONIDINE	64	130	88
28	42	M	cholelithiasis	lap cholecystectomy	180min	DEXMEDETOMIDINE	84	138	72
29	19	M	Cholelithasis	lap cholecystectomy	120min	CLONIDINE	110	118	79
30	52	F	gall stone disease	lap cholecystectomy	100min	CLONIDINE	76	138	80

									BASELINE
S.no	Age	Sex	Diagnosis	Operation	Duration	Drug given	HR	SBP	DBP
31	40	F	cholelithiasis	lap cholecystectomy	180min	DEXMEDETOMIDINE	93	138	95
32	42	F	cholelithiasis	lap cholecystectomy	150min	DEXMEDETOMIDINE	88	114	76
33	34	M	cholelithiasis	lap cholecystectomy	240min	DEXMEDETOMIDINE	78	134	85
34	30	F	cholelithiasis	lap cholecystectomy	180 min	CLONIDINE	82	116	80
35	38	F	cholelithiasis	lap cholecystectomy	180min	CLONIDINE	78	113	78
36	32	F	cholelithiasis	lap cholecystectomy	140min	DEXMEDETOMIDINE	82	116	75
37	52	M	gall stone disease	lap cholecystectomy	180min	CLONIDINE	68	135	72
38	23	F	cholelithiasis	lap cholecystectomy	150min	CLONIDINE	105	114	78
39	34	M	cholelithiasis	lap cholecystectomy	240min	DEXMEDETOMIDINE	82	138	86
40	39	M	cholelithiasis	lap cholecystectomy	90min	DEXMEDETOMIDINE	88	132	65
41	42	M	cholelithiasis	lap cholecystectomy	150min	DEXMEDETOMIDINE	90	142	79
42	37	F	gall stone disease	lap cholecystectomy	200min	CLONIDINE	82	118	74
43	49	M	cholelithiasis	lap cholecystectomy	150min	DEXMEDETOMIDINE	65	144	93
44	48	F	gall stone disease	lap cholecystectomy	200 min	DEXMEDETOMIDINE	69	130	84
45	40	F	gall stone disease	lap cholecystectomy	110 min	CLONIDINE	80	135	80
46	37	M	gall stone disease	lap cholecystectomy	200 min	DEXMEDETOMIDINE	76	139	72
47	42	F	cholelithiasis	lap cholecystectomy	180 min	CLONIDINE	68	124	80
48	32	M	cholelithiasis	lap cholecystectomy	160min	DEXMEDETOMIDINE	72	112	65
49	25	M	gall stone disease	lap cholecystectomy	80 min	CLONIDINE	74	120	80
50	47	F	cholelithiasis	lap cholecystectomy	180min	CLONIDINE	70	136	70
51	45	M	cholelithiasis	lap cholecystectomy	170min	DEXMEDETOMIDINE	92	124	94
52	57	M	cholelithiasis	lap cholecystectomy	200min	DEXMEDETOMIDINE	70	140	88
53	36	M	cholelithiasis	lap cholecystectomy	180min	CLONIDINE	92	120	72
54	65	M	gall stone disease	lap cholecystectomy	120min	DEXMEDETOMIDINE	76	134	92
55	43	F	cholelithiasis	lap cholecystectomy	180min	CLONIDINE	89	130	86
56	50	F	cholelithiasis	lap cholecystectomy	170	CLONIDINE	68	140	90
57	38	M	gall stone disease	lap cholecystectomy	180min	CLONIDINE	76	139	94
58	36	F	gall stone disease	lap cholecystectomy	200min	CLONIDINE	120	118	72
59	38	M	gall stone disease	lap cholecystectomy	200min	CLONIDINE	85	132	80
60	52	M	cholelithiasis	lap cholecystectomy	150min	CLONIDINE	68	124	74

									BASELINE
S.no	Age	Sex	Diagnosis	Operation	Duration	Drug given	HR	SBP	DBP
61	48	M	gall stone disease	lap cholecystectomy	160min	DEXMEDETOMIDINE	89	128	76
62	40	F	gall stone disease	lap cholecystectomy	200 min	DEXMEDETOMIDINE	86	126	85
63	35	M	Cholelithiasis	lap cholecystectomy	180min	CLONIDINE	70	126	85
64	29	M	cholelithiasis	lap cholecystectomy	90min	CLONIDINE	110	114	70
65	41	M	cholelithiasis	lap cholecystectomy	120 min	DEXMEDETOMIDINE	82	135	93
66	56	M	cholelithiasis	lap cholecystectomy	120min	DEXMEDETOMIDINE	89	138	97
67	24	M	cholelithiasis	lap cholecystectomy	90min	CLONIDINE	74	135	83
68	36	M	cholelithiasis	lap cholecystectomy	180min	DEXMEDETOMIDINE	90	115	70
69	25	F	cholelithiasis	lap cholecystectomy	180min	DEXMEDETOMIDINE	92	107	77
70	51	M	Cholelithiasis	lap cholecystectomy	200min	DEXMEDETOMIDINE	76	154	93
71	29	M	Cholelithiasis	lap cholecystectomy	250min	CLONIDINE	76	133	84
72	40	F	Cholelithiasis	lap cholecystectomy	110min	CLONIDINE	88	140	90
73	32	F	Cholelithiasis	lap cholecystectomy	250min	CLONIDINE	90	122	73
74	60	M	Cholelithiasis	lap cholecystectomy	200min	DEXMEDETOMIDINE	76	138	95
75	36	F	cholelilithiasis	lap cholecystectomy	180min	CLONIDINE	69	139	70
76	44	F	cholelithiasis	lap cholecystectomy	150min	CLONIDINE	70	128	84
77	48	M	sealed GB perforation	lap cholecystectomy	170min	DEXMEDETOMIDINE	67	139	80
78	52	M	cholelithiasis	lap cholecystectomy	130min	DEXMEDETOMIDINE	78	142	80
79	50	M	gall stone disease	lap cholecystectomy	190min	CLONIDINE	74	136	80
80	33	F	gall stone disease	lap cholecystectomy	120min	CLONIDINE	85	128	78

																VITALS
						AT INDUCTION					AT LARYNGOSCOPY					AT INTUBATION
S.no	Age	Sex	MAP	SPO2	HR	SBP	DBP	MAP	SPO2	HR	SBP	DBP	MAP	SPO2	HR	SBP
1	30	F	90	100	71	102	49	82	100	101	114	50	62	99	76	114
2	27	F	96	100	84	82	53	64	100	90	82	53	64	100	78	112
3	29	F	103	100	84	124	103	111	100	85	135	96	114	100	85	123
4	57	F	112	100	97	121	77	100	98	101	100	67	80	100	95	113
5	39	F	93	100	87	107	66	81	100	87	142	90	110	100	96	142
6	52	M	125	99	72	116	86	110	97	73	130	106	119	100	90	141
7	37	F	80	100	80	108	80	82	100	89	108	82	84	100	89	118
8	52	F	109	100	65	145	92	109	100	65	140	90	106	100	65	135
9	30	M	92	100	80	135	69	91	100	84	140	76	97	100	84	138
10	58	F	90	100	84	109	69	85	99	84	150	90	120	100	78	132
11	42	M	103	98	97	113	77	92	99	95	137	109	120	100	95	137
12	32	M	82	100	75	100	58	65	100	88	101	63	64	100	74	108
13	25	F	80	100	68	123	80	100	100	69	119	67	93	100	66	94
14	32	M	90	100	76	116	78	65	100	78	120	76	70	100	78	122
15	48	F	103	100	70	130	82	95	100	90	138	89	86	100	92	140
16	38	F	100	100	96	130	82	60	100	89	130	82	104	100	105	95
17	47	F	105	100	64	130	70	98	100	98	128	65	102	100	90	138
18	32	M	95	100	85	106	79	90	100	85	127	82	99	100	74	127
19	36	M	90	100	100	128	86	100	100	92	128	86	100	100	99	125
20	60	M	117	98	79	128	68	88	100	70	110	56	79	100	81	90
21	43	F	101	100	74	108	83	92	100	74	87	62	73	100	74	108
22	31	M	104	100	75	112	65	82	100	79	124	82	98	100	85	121
23	30	F	85	100	109	86	46	62	100	99	108	63	84	100	90	91
24	38	F	102	100	89	119	69	89	100	96	112	71	88	100	96	108
25	52	M	93	100	76	89	58	69	100	92	122	92	92	100	93	122
26	55	F	91	100	85	95	63	77	100	85	94	62	76	100	96	92
27	35	M	102	100	75	108	67	83	100	90	138	89	85	100	94	165
28	42	M	92	100	91	124	65	85	100	92	123	54	78	100	92	118
29	19	M	95	100	84	86	54	66	100	90	82	54	64	100	77	112
30	52	F	103	100	85	138	94	104	100	85	132	96	113	100	85	132

																VITALS
						AT INDUCTION					AT LARYNGOSCOPY					AT INTUBATION
S.no	Age	Sex	MAP	SPO2	HR	SBP	DBP	MAP	SPO2	HR	SBP	DBP	MAP	SPO2	HR	SBP
31	40	F	113	100	97	126	70	108	100	101	123	68	84	100	90	126
32	42	F	92	100	87	108	66	80	100	82	140	90	108	100	96	142
33	34	M	94	100	76	116	80	90	100	84	130	96	102	100	91	140
34	30	F	93	100	78	108	64	74	100	80	108	65	78	100	82	115
35	38	F	83	100	76	109	56	72	100	80	118	72	85	100	84	113
36	32	F	90	100	86	108	66	80	100	80	139	90	102	100	90	142
37	52	M	95	100	70	132	85	94	100	72	128	70	80	100	78	130
38	23	F	85	100	78	94	52	66	100	88	98	54	64	100	78	112
39	34	M	95	100	82	115	70	88	100	92	132	98	102	100	89	138
40	39	M	85	100	69	100	52	78	100	100	118	58	70	99	74	119
41	42	M	98	100	86	128	60	89	100	95	126	64	80	100	85	112
42	37	F	80	100	89	109	74	82	100	94	108	76	86	100	90	124
43	49	M	109	100	66	146	93	108	100	68	143	92	108	100	70	135
44	48	F	104	100	72	133	83	98	100	90	138	90	93	100	94	142
45	40	F	94	99	82	128	72	85	99	84	140	90	105	99	70	132
46	37	M	93	100	78	135	70	91	100	84	142	68	96	100	86	136
47	42	F	104	98	94	120	79	94	99	86	134	102	108	100	85	132
48	32	M	83	100	74	100	54	68	100	80	102	66	70	100	70	105
49	25	M	90	99	78	124	82	84	100	69	118	70	86	100	67	123
50	47	F	102	100	68	134	73	99	100	88	126	58	85	100	90	132
51	45	M	100	100	96	130	82	104	100	89	130	82	104	100	105	95
52	57	M	93	100	76	110	75	89	100	82	130	84	89	100	78	123
53	36	M	93	100	96	132	80	102	100	94	136	85	104	100	86	130
54	65	M	108	98	80	126	65	85	100	83	112	54	82	100	82	93
55	43	F	102	100	78	109	84	93	100	89	113	65	76	100	88	114
56	50	F	106	100	72	142	90	105	100	70	136	85	88	100	65	132
57	38	M	108	99	75	118	64	85	100	79	126	84	90	100	83	121
58	36	F	90	100	108	107	58	66	100	95	108	64	83	100	95	126
59	38	M	70	100	95	128	72	75	100	90	130	84	77	100	94	120
60	52	M	92	100	70	104	60	74	100	74	126	90	96	100	96	130

																VITALS
						AT INDUCTION					AT LARYNGOSCOPY					AT INTUBATION
S.no	Age	Sex	MAP	SPO2	HR	SBP	DBP	MAP	SPO2	HR	SBP	DBP	MAP	SPO2	HR	SBP
61	48	M	93	100	86	116	64	78	100	83	108	65	72	100	94	92
62	40	F	100	100	90	119	70	93	100	98	123	70	88	100	94	106
63	35	M	96	100	76	111	68	86	100	93	142	93	98	100	92	148
64	29	M	94	100	85	94	54	68	100	90	98	62	70	100	84	118
65	41	M	108	100	84	128	84	102	100	94	124	70	94	100	96	120
66	56	M	108	92	126	79	99	98	100	102	100	84	66	100	127	72
67	24	M	94	100	80	126	76	98	100	85	132	85	102	100	90	124
68	36	M	94	100	87	108	68	85	100	90	138	90	102	100	92	136
69	25	F	88	100	68	123	80	100	100	69	119	67	93	100	66	94
70	51	M	115	100	79	124	88	102	100	82	132	96	92	100	88	139
71	29	M	89	100	70	109	68	80	100	74	122	80	95	100	88	124
72	40	F	108	100	80	121	70	99	100	78	130	69	87	100	86	128
73	32	F	90	100	86	128	80	87	100	80	132	78	82	100	77	140
74	60	M	108	100	80	126	65	85	100	83	112	54	82	100	76	96
75	36	F	105	100	68	134	74	98	100	84	126	64	85	100	90	132
76	44	F	95	100	78	119	70	85	100	80	130	89	92	100	88	135
77	48	M	98	100	70	140	90	102	100	69	138	89	90	100	76	128
78	52	M	97	100	87	128	68	87	100	88	131	72	89	100	92	116
79	50	M	91	100	82	139	92	87	100	75	129	78	82	100	89	135
80	33	F	93	100	80	135	78	91	100	86	136	72	94	100	70	127

						1 MINUTE AFTER INTUBATION					5 MINUTE AFTER INTUBATION			
S.no	Age	Sex	DBP	MAP	SPO2	HR	SBP	DBP	MAP	SPO2	HR	SBP	DBP	MAP
1	30	F	50	62	100	78	114	50	62	100	90	106	63	79
2	27	F	65	95	100	85	84	53	64	100	106	109	80	97
3	29	F	74	92	100	71	101	59	76	100	64	108	65	81
4	57	F	70	88	100	83	87	59	71	100	81	121	87	103
5	39	F	90	110	100	87	107	69	86	100	82	115	78	93
6	52	M	87	111	100	79	130	78	102	100	66	134	90	107
7	37	F	79	82	100	90	100	70	82	100	83	100	70	82
8	52	F	88	103	100	65	118	68	84	100	64	106	58	80
9	30	M	76	96	100	80	128	70	89	100	74	114	68	83
10	58	F	82	90	99	65	95	57	75	100	67	92	62	75
11	42	M	109	120	100	70	145	85	103	100	74	128	72	89
12	32	M	64	69	100	74	100	50	59	100	72	120	80	75
13	25	F	40	62	100	65	108	74	86	100	52	134	82	101
14	32	M	80	70	100	68	111	70	75	100	61	102	60	80
15	48	F	95	112	100	84	120	74	84	100	84	110	68	70
16	38	F	60	70	100	88	84	50	62	100	80	124	68	70
17	47	F	90	106	100	67	90	59	73	100	63	82	51	64
18	32	M	82	99	100	66	95	52	71	100	65	99	55	74
19	36	M	82	82	100	84	124	73	103	100	73	94	59	76
20	60	M	54	67	100	76	119	59	78	100	72	120	62	79
21	43	F	83	92	100	69	108	83	92	100	70	93	51	68
22	31	M	68	89	100	84	112	64	85	100	75	128	73	94
23	30	F	54	80	100	88	94	50	70	100	106	120	78	98
24	38	F	65	85	100	85	100	58	69	100	70	112	70	70
25	52	M	92	96	100	89	96	64	78	100	88	91	57	71
26	55	F	57	73	100	89	79	48	62	100	97	102	66	79
27	35	M	114	138	100	97	127	83	102	100	107	97	58	72
28	42	M	68	70	100	88	102	60	70	100	78	100	54	65
29	19	M	62	90	100	85	90	52	68	100	90	108	80	89
30	52	F	96	113	100	85	130	74	95	100	70	108	64	77

						1 MINUTE AFTER INTUBATION					5 MINUTE AFTER INTUBATION			
S.no	Age	Sex	DBP	MAP	SPO2	HR	SBP	DBP	MAP	SPO2	HR	SBP	DBP	MAP
31	40	F	70	89	100	84	90	60	70	99	79	79	123	86
32	42	F	92	110	100	79	118	70	88	100	76	115	72	83
33	34	M	87	111	100	70	130	73	96	100	65	130	90	107
34	30	F	60	82	100	70	100	56	69	100	66	120	64	73
35	38	F	65	87	100	69	104	54	64	100	63	124	56	72
36	32	F	93	110	100	76	123	70	88	100	70	118	72	85
37	52	M	68	90	100	66	108	64	74	100	63	105	60	80
38	23	F	63	96	100	80	98	54	68	100	72	110	80	72
39	34	M	98	105	100	78	124	70	96	100	68	132	92	105
40	39	M	62	69	100	68	100	58	79	100	84	123	54	72
41	42	M	68	68	100	86	100	58	70	100	76	98	52	66
42	37	F	80	85	100	86	102	64	85	100	70	120	68	70
43	49	M	80	104	100	68	118	70	90	100	64	107	59	85
44	48	F	96	110	100	85	130	78	89	100	88	109	67	74
45	40	F	80	90	99	70	104	70	69	100	66	94	60	70
46	37	M	72	94	100	87	128	69	90	100	72	118	65	85
47	42	F	94	104	100	82	128	68	94	100	74	114	73	89
48	32	M	60	72	100	72	108	54	74	100	70	120	86	85
49	25	M	74	90	100	70	109	69	85	100	72	108	65	83
50	47	F	89	102	100	69	93	56	72	100	63	108	58	68
51	45	M	60	70	100	105	95	60	70	100	88	84	50	62
52	57	M	76	90	100	67	96	50	70	100	64	110	58	68
53	36	M	75	95	100	84	123	70	89	100	70	98	62	78
54	65	M	54	66	100	72	120	70	66	100	80	124	60	80
55	43	F	80	94	100	75	117	86	91	100	75	117	86	91
56	50	F	80	83	100	65	135	82	84	100	58	108	59	62
57	38	M	68	78	100	80	119	65	86	100	75	128	74	93
58	36	F	68	75	100	86	112	68	72	100	86	123	76	98
59	38	M	76	68	100	80	123	58	62	100	75	108	59	64
60	52	M	94	182	100	90	99	66	76	100	80	96	52	68

						1 MINUTE AFTER INTUBATION					5 MINUTE AFTER INTUBATION			
S.no	Age	Sex	DBP	MAP	SPO2	HR	SBP	DBP	MAP	SPO2	HR	SBP	DBP	MAP
61	48	M	58	78	100	86	98	57	69	100	78	108	68	83
62	40	F	71	89	100	88	107	63	74	100	74	123	74	80
63	35	M	98	106	100	96	132	90	92	100	86	99	61	75
64	29	M	70	93	100	93	96	58	73	100	108	109	80	98
65	41	M	76	91	100	88	95	62	75	100	84	126	89	94
66	56	M	87	100	84	95	62	70	75	99	80	123	82	85
67	24	M	73	95	100	84	104	64	80	100	80	112	70	85
68	36	M	88	83	100	84	118	72	94	100	78	124	82	104
69	25	F	40	62	100	65	108	74	86	100	52	134	82	101
70	51	M	89	107	100	77	126	82	90	100	68	132	90	89
71	29	M	88	90	100	80	119	65	85	100	70	126	68	86
72	40	F	70	79	100	70	108	70	69	100	80	118	65	70
73	32	F	98	102	100	78	130	82	92	100	70	129	78	89
74	60	M	54	65	100	72	112	70	73	100	80	124	60	79
75	36	F	88	102	100	68	96	53	68	100	65	108	58	68
76	44	F	92	86	100	78	128	80	83	100	80	100	58	86
77	48	M	70	85	100	80	138	90	94	100	68	118	63	78
78	52	M	70	76	100	76	121	73	80	100	78	128	83	78
79	50	M	89	95	100	73	125	83	82	100	69	122	76	93
80	33	F	69	90	100	74	118	65	83	100	70	114	70	84

					AFTER EXTUBATION					
S.no	Age	Sex	SPO2	HR	SBP	DBP	MAP	SPO2	AIRWAY PRESSURE	ETT INTRA CUFF PRESSURE
1	30	F	100	108	118	72	87	100	16	30
2	27	F	100	108	114	70	85	100	16	30
3	29	F	100	68	134	80	100	100	16	28
4	57	F	100	96	104	97	121	100	20	30
5	39	F	100	72	116	70	92	100	21	26
6	52	M	100	100	118	65	90	100	14	30
7	37	F	100	88	110	84	85	100	18	28
8	52	F	100	58	132	90	104	100	17	28
9	30	M	100	70	114	70	83	100	18	28
10	58	F	100	88	128	74	80	100	15	25
11	42	M	100	86	132	84	78	100	15	30
12	32	M	100	92	124	88	78	100	12	22
13	25	F	100	92	117	68	80	100	15	35
14	32	M	100	110	140	85	90	100	16	29
15	48	F	100	68	132	86	102	100	16	30
16	38	F	100	108	130	80	95	100	26	30
17	47	F	100	70	119	70	85	100	15	30
18	32	M	100	85	108	54	68	100	18	31
19	36	M	100	77	116	70	82	100	18	28
20	60	M	100	80	124	80	88	100	17	28
21	43	F	100	89	128	78	90	100	20	30
22	31	M	100	78	130	88	95	100	15	30
23	30	F	100	102	118	65	80	100	14	28
24	38	F	100	84	124	86	89	100	13	30
25	52	M	100	70	139	88	102	100	16	32
26	55	F	100	67	111	56	88	100	20	30
27	35	M	98	68	128	85	70	100	18	30
28	42	M	100	65	128	68	75	100	18	30
29	19	M	100	82	115	70	88	100	16	30
30	52	F	100	68	140	86	108	100	17	27

					AFTER EXTUBATION					
S.no	Age	Sex	SPO2	HR	SBP	DBP	MAP	SPO2	AIRWAY PRESSURE	ETT INTRA CUFF PRESSURE
31	40	F	100	99	84	114	92	100	20	30
32	42	F	100	67	123	70	92	100	21	32
33	34	M	100	82	116	64	89	100	14	29
34	30	F	100	80	106	54	80	100	15	28
35	38	F	100	78	118	70	72	100	18	28
36	32	F	100	64	120	70	92	100	21	26
37	52	M	100	67	138	84	108	100	17	27
38	23	F	100	82	115	70	88	100	16	30
39	34	M	100	70	114	62	89	100	14	28
40	39	M	100	74	119	62	69	100	16	30
41	42	M	100	65	124	67	70	100	18	25
42	37	F	100	94	124	80	86	100	16	25
43	49	M	100	58	130	85	102	100	20	30
44	48	F	100	67	134	85	94	100	16	30
45	40	F	100	66	94	60	75	100	18	26
46	37	M	100	68	123	70	84	100	18	30
47	42	F	98	68	124	70	94	100	15	30
48	32	M	100	86	124	89	93	100	12	26
49	25	M	100	84	138	94	102	100	18	25
50	47	F	100	70	123	64	90	100	15	25
51	45	M	100	88	84	50	62	100	22	28
52	57	M	100	68	134	89	76	100	16	32
53	36	M	100	70	124	64	80	100	18	30
54	65	M	100	84	132	68	80	100	17	30
55	43	F	100	70	94	52	70	100	20	30
56	50	F	100	65	136	85	73	100	18	30
57	38	M	100	79	126	84	90	100	15	30
58	36	F	100	106	126	82	83	100	18	30
59	38	M	100	75	118	72	68	100	18	30
60	52	M	100	76	123	69	74	100	17	26

					AFTER EXTUBATION					
S.no	Age	Sex	SPO2	HR	SBP	DBP	MAP	SPO2	AIRWAY PRESSURE	ETT INTRA CUFF PRESSURE
61	48	M	100	74	124	65	86	100	20	30
62	40	F	100	80	118	85	93	100	13	27
63	35	M	98	68	128	80	73	100	18	30
64	29	M	100	78	129	75	102	100	16	30
65	41	M	99	72	124	79	102	100	19	30
66	56	M	73	108	80	93	100	100	21	26
67	24	M	100	70	123	70	90	100	16	23
68	36	M	100	65	112	65	94	100	21	30
69	25	F	100	92	117	68	92	100	15	25
70	51	M	100	84	124	70	78	100	14	30
71	29	M	100	80	136	90	96	100	18	24
72	40	F	100	68	119	70	71	100	20	30
73	32	F	100	70	123	76	80	100	18	25
74	60	M	100	84	123	70	80	100	17	30
75	36	F	100	70	123	65	89	100	19	28
76	44	F	100	68	130	82	88	100	18	30
77	48	M	100	54	130	87	95	100	20	30
78	52	M	100	65	124	68	75	100	18	26
79	50	M	100	73	130	85	105	100	17	27
80	33	F	100	70	114	70	83	100	18	28

			DURING GAS INSUFFLATION OF ABDOMEN		EXTUBATION
S.no	Age	Sex	AIRWAY PRESSURE	ETT INTRA CUFF PRESSURE	AIRWAY PRESSURE
1	30	F	21	30	18
2	27	F	18	30	16
3	29	F	22	28	22
4	57	F	26	30	19
5	39	F	21	26	20
6	52	M	22	30	15
7	37	F	21	28	14
8	52	F	21	28	16
9	30	M	22	28	18
10	58	F	21	25	14
11	42	M	18	30	15
12	32	M	16	22	12
13	25	F	20	30	16
14	32	M	19	30	20
15	48	F	22	30	15
16	38	F	20	30	22
17	47	F	23	30	17
18	32	M	18	31	17
19	36	M	23	28	18
20	60	M	26	28	20
21	43	F	24	30	20
22	31	M	21	30	17
23	30	F	25	28	15
24	38	F	22	30	15
25	52	M	18	32	12
26	55	F	24	30	19
27	35	M	22	30	19
28	42	M	22	30	19
29	19	M	18	30	16
30	52	F	24	27	17

			DURING GAS INSUFFLATION OF ABDOMEN		EXTUBATION
S.no	Age	Sex	AIRWAY PRESSURE	ETT INTRA CUFF PRESSURE	AIRWAY PRESSURE
31	40	F	26	30	19
32	42	F	25	32	20
33	34	M	22	29	15
34	30	F	22	28	14
35	38	F	22	28	14
36	32	F	25	26	20
37	52	M	24	27	17
38	23	F	18	30	16
39	34	M	22	28	15
40	39	M	21	30	19
41	42	M	22	25	19
42	37	F	24	25	14
43	49	M	25	30	18
44	48	F	22	30	15
45	40	F	23	26	16
46	37	M	22	30	18
47	42	F	19	30	15
48	32	M	16	26	12
49	25	M	19	28	20
50	47	F	22	28	16
51	45	M	29	28	22
52	57	M	18	23	16
53	36	M	23	30	17
54	65	M	25	30	18
55	43	F	26	30	25
56	50	F	25	28	24
57	38	M	21	30	16
58	36	F	22	30	15
59	38	M	22	30	15
60	52	M	18	26	13

			DURING GAS INSUFFLATION OF ABDOMEN		EXTUBATION
S.no	Age	Sex	AIRWAY PRESSURE	ETT INTRA CUFF PRESSURE	AIRWAY PRESSURE
61	48	M	24	30	19
62	40	F	21	27	14
63	35	M	22	30	19
64	29	M	18	30	16
65	41	M	26	30	19
66	56	M	12	26	19
67	24	M	24	23	13
68	36	M	25	30	20
69	25	F	20	25	16
70	51	M	22	30	14
71	29	M	21	24	16
72	40	F	26	30	25
73	32	F	23	25	17
74	60	M	25	30	18
75	36	F	22	28	16
76	44	F	22	30	19
77	48	M	25	30	19
78	52	M	22	26	19
79	50	M	24	27	18
80	33	F	22	28	18

					SORE THROAT EVALUATION			
S.no	Age	Sex	ETT INTRA CUFF PRESSURE	10 MINUTES	1 HR	6 HR	12 HR`	24 HR
1	30	F	30	0	0	1	1	0
2	27	F	28	0	0	0	0	0
3	29	F	28	0	0	0	1	1
4	57	F	30	0	0	0	0	0
5	39	F	26	0	0	0	0	0
6	52	M	30	0	0	1	0	0
7	37	F	28	0	0	2	1	0
8	52	F	28	0	0	0	0	0
9	30	M	28	0	0	0	0	0
10	58	F	25	0	0	1	1	0
11	42	M	30	0	0	2	1	0
12	32	M	22	0	0	0	0	0
13	25	F	30	0	0	2	2	2
14	32	M	30	0	0	1	0	0
15	48	F	25	0	0	0	0	0
16	38	F	26	0	0	0	0	0
17	47	F	30	2	1	0	0	0
18	32	M	31	0	0	0	0	0
19	36	M	28	0	0	0	0	0
20	60	M	28	0	0	0	0	0
21	43	F	30	0	0	1	1	0
22	31	M	30	0	0	0	0	0
23	30	F	28	0	0	0	0	0
24	38	F	30	0	1	0	0	0
25	52	M	32	0	0	1	1	0
26	55	F	30	0	0	0	0	0
27	35	M	27	0	0	1	0	0
28	42	M	30	0	0	0	0	0
29	19	M	26	0	0	0	0	1
30	52	F	27	0	0	0	1	1

					SORE THROAT EVALUATION			
S.no	Age	Sex	ETT INTRA CUFF PRESSURE	10 MINUTES	1 HR	6 HR	12 HR`	24 HR
31	40	F	25	0	0	0	0	0
32	42	F	32	0	0	0	1	0
33	34	M	29	0	0	0	0	0
34	30	F	28	0	0	2	1	0
35	38	F	28	0	0	2	1	0
36	32	F	26	0	0	0	1	0
37	52	M	27	0	0	0	1	1
38	23	F	30	0	0	0	0	1
39	34	M	28	0	0	0	0	0
40	39	M	30	0	0	1	1	0
41	42	M	25	0	0	0	0	0
42	37	F	25	0	0	2	1	0
43	49	M	30	0	0	0	0	0
44	48	F	30	0	0	0	0	0
45	40	F	26	0	1	1	0	0
46	37	M	30	0	0	0	0	0
47	42	F	25	0	0	2	1	0
48	32	M	26	0	0	0	0	0
49	25	M	28	0	0	1	0	0
50	47	F	28	0	1	0	0	0
51	45	M	28	0	0	0	0	0
52	57	M	23	0	0	0	0	0
53	36	M	30	0	0	0	0	0
54	65	M	26	0	0	0	0	0
55	43	F	30	0	0	1	1	0
56	50	F	30	0	0	1	0	0
57	38	M	30	0	0	0	0	0
58	36	F	30	0	0	0	0	0
59	38	M	30	0	0	0	0	0
60	52	M	26	0	0	1	1	0

					SORE THROAT EVALUATION			
S.no	Age	Sex	ETT INTRA CUFF PRESSURE	10 MINUTES	1 HR	6 HR	12 HR`	24 HR
61	48	M	26	0	0	0	0	0
62	40	F	27	0	0	0	0	0
63	35	M	30	0	0	1	0	0
64	29	M	30	0	0	0	0	0
65	41	M	30	0	0	0	0	0
66	56	M	26	0	0	0	0	0
67	24	M	23	0	0	0	1	1
68	36	M	30	0	0	0	0	0
69	25	F	25	0	0	0	0	0
70	51	M	30	0	0	1	0	0
71	29	M	24	0	0	0	0	0
72	40	F	30	0	0	1	1	0
73	32	F	25	0	0	0	0	0
74	60	M	30	0	0	0	0	0
75	36	F	28	0	1	2	0	0
76	44	F	26	0	0	1	1	0
77	48	M	25	0	0	0	0	0
78	52	M	26	0	0	0	0	0
79	50	M	27	0	0	0	1	1
80	33	F	28	0	0	0	0	0